CORE CLINICAL STUDY
AUGMENTATION COHORT

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ABSTRACT

The McGhan Medical Corporation Silicone-Filled Breast Implant Core Clinical Study is a prospective, 10-year, multi-center clinical study conducted to examine the safety and effectiveness of McGhan Silicone-Filled Breast Implants for augmentation, reconstruction, and revision patients. This report presents the results from the augmentation cohort through 2 years post-implant.

Data from 494 patients who received 987 silicone-filled breast implants for the purpose of unilateral or bilateral augmentation of the breast are presented in this report. The extract date of the database used for this report is August 30, 2002. The augmentation patients were enrolled between January 6, 1999 and June 30, 2000. The majority of patients are Caucasian with a median age at study entry of 34 years.

The primary safety data collected in this study are complications (e.g., device rupture, capsular contracture) and reoperations involving the breast/chest area (e.g., implant replacement/removal). Additionally, all post-implant reports of reproduction/lactation problems, connective tissue/autoimmune disease, and breast disease/carcinoma are documented. Safety data is collected at scheduled follow-up intervals (0-4 weeks, 6 months, and annually at 1-10 years post-implant) as well as during unscheduled visits.

Several types of effectiveness data are collected. First, pre- and post-implant breast size measurements are obtained to assess whether breast implant surgery achieved the desired objective of increasing the size of the breast. Second, at all scheduled follow-up visits, both the patient's and the physician's level of satisfaction with the breast implantation are assessed. Finally, prior to implantation and at 1, 2, 4, 6, 8, and 10 years post-implant patients complete a questionnaire to assess their quality of life covering a variety of parameters, including general health, self-esteem, and body image.

As of this report, 10 (2.0%) of the 494 patients initially enrolled (implanted) have been discontinued from the study. Eight (8) of the 10 patients were discontinued due to permanent removal of all study devices and 2 patients chose to discontinue. Taking into account patients who died or had all study devices removed without replacement with other study devices, follow-up compliance was 85.7% at the 1-year follow-up visit and 89.8% at the 2-year follow-up visit. No patients died during the period of this report.

To estimate the risk of complications following implantation, Kaplan-Meier survival analysis was conducted on the time to first occurrence of each event. To assess change in quality of life among the three available measured time points (baseline/pre-implantation, 1 year post-implant, and 2 years post-implant), a repeated-measures analysis of variance was conducted on the mean score for each quality of life scale.

Table 1 of this abstract summarizes the 2-year by-patient risk rate associated with various complications, including the following types of outcomes:

- General Breast Surgery Complications (e.g., breast pain)
- Breast Implant Surgery – Cosmetic Complications (e.g., wrinkling/rippling, implant palpability)
- Breast Implant Surgery – Non-Cosmetic Complications (e.g., capsular contracture, implant extrusion)

The complications with the highest 2-year risk rate by patient were swelling (6.8%), capsular contracture (6.7%), and breast pain (5.0%). All of the swelling complications occurred within 1 year of implantation. All other complications occurred at a by-patient risk rate of less than 4.0%. Overall, more than three fourths (80.0%) of complications were resolved within the period of this report. Of those complications that were resolved, most (76.2%) were resolved either without treatment or with non-surgical treatment.

A total of 9 devices were suspected of rupture through 2 years post-implant. Three (3) of the 9 devices have been explanted and the remaining 6 devices are still implanted. Of the 9 suspected device ruptures, 5 devices were found to be intact (i.e., false reports of rupture), 2 devices were confirmed ruptured, and 2 devices remain unconfirmed ruptures. Based on confirmed and unconfirmed ruptures, the 2-year by-patient risk of implant rupture was 0.9%.

A total of 81 patients underwent 91 reoperations through 2 years post-implant, with a 2-year by-patient risk of reoperation of 17.1%. Of the 91 reoperations, the most common procedures performed were implant removal with replacement (23.1%), capsulotomy (15.4%), and mastopexy (13.2%).

By the end of the 2-year post-implant visit, 22 patients had 41 study devices removed, with a 2-year by-patient risk of implant replacement/removal for any reason of 4.7%. Of the 41 devices that were explanted, 19 (46.3%) were removed due to capsular contracture and 7 (17.1%) were removed due to patient request for style/size change. Most devices (95.1%) were replaced.

Eighty-one (81) patients (16.4%) reported reproduction problems prior to implantation. The most prevalent problems were spontaneous abortion/miscarriage and infertility. Five (5) patients (1.0%) had 5 reports of post-implant reproduction problems through 2 years, of which 4 were spontaneous abortions/miscarriages and 1 was endometriosis. One of the 5 patients who had a post-implant reproduction problem also had a pre-implant reproduction problem.

Forty-two (42) patients (8.5%) reported lactation problems prior to implantation, most commonly inadequate milk production and mastitis that required treatment. Four patients (0.8%) had 8 reports of post-implant lactation problems through 2 years, of which 1 was mastitis with no treatment required, 2 were mastitis that required treatment, 2 were inadequate milk production, 1 was excess milk production, 1 was pain, and 1 was "decrease [*sic*] volume milk (still adequate)".

Thirty (30) patients (6.1%) reported breast disease prior to implantation, of which 29 were benign breast disease and 1 was unknown breast disease. Twenty-seven (27) patients (5.5%) had reports of post-implant breast disease through 2 years, of which 1 was confirmed malignant disease, 25 were benign breast disease, and 1 was a report of a breast lump for which the outcome (benign or malignant) was not known at the time of the data extract. Four (4) of the 25 patients who had post-implant benign breast disease also had pre-implant benign breast disease.

None of the patients reported connective tissue/autoimmune disease (CTD) prior to implantation. One (1) patient reported a CTD through 2 years post implant. This 46-year old patient had a confirmed diagnosis of rheumatoid arthritis with an onset date of 18 months after implant surgery.

The majority of patients increased the size of their breasts by one or two cup sizes (40.4% and 45.3%, respectively) pre- vs. post- implant. The remaining patients increased by more than two cup sizes (8.3%), maintained the same cup size (5.4%), or showed a decrease in cup size (0.5%). For these latter patients, a cup size increase was not observed for a variety of reasons, including the purpose of implant surgery (e.g., to improve the shape and fullness of the breast, to correct congenital asymmetry) and an atypical pre-implant breast measurement (e.g., larger than normal cup size due to menstruation).

More than 95% of both physicians and patients indicated being satisfied with the outcome of the breast implant surgery at each of the four follow-up visit intervals. Indeed, on a 1 (definitely dissatisfied) to 5 (definitely satisfied) scale, the average satisfaction level for physicians and patients ranged between 4.8 and 4.9 during each follow-up interval.

Quality of life results are summarized in Table 2 of this abstract. As measured by the "SF-36 Status Survey", the population of women participating in this clinical study indicated a higher quality of life than the general U.S. female population. On each of the eight scales for which comparative values are available, the women in this study scored between 11 and 20 points higher on average at baseline (out of 100 total points) than the comparison group.

A number of quality of life domains were assessed: general health and physical/mental well being (e.g., the SF-36 and MOS-20 surveys), self-related concepts (e.g., physical self concept and self esteem), and breast-related concepts (e.g., satisfaction with breast size and shape). Table 2 of this abstract summarizes the results pertaining to changes in quality of life pre-implant/baseline vs. 1 year post-implant. Similar changes in quality of life were observed comparing pre-implant to 2-year post-implant results.

For half of the general health concepts, average scores at 1 year post-implant were statistically significantly lower vs. baseline. However, the magnitude of the differences was small and the post-implant quality of life scores remained well above those of the general population. In contrast, most of the specific measures of self- and breast-related concepts showed significantly higher scores at 1 year post-implant vs. baseline, and the magnitude of the difference was generally large. Patients' satisfaction with their breasts on a variety of assessments (e.g., breast shape, size, feel) showed substantial increases at 1 year vs. baseline.

Table 1. Core Clinical Study – Augmentation Cohort Summary of 2-Year Risk Rate for Specific Complications		
Complication	**2-Year Risk By Patient**	**2-Year Risk By Implant**
Swelling	6.8%	5.6%
Capsular Contracture	6.7%	5.1%
Breast Pain	5.0%	3.3%
Loss of Nipple Sensation	3.1%	2.4%
Implant Malposition	2.5%	1.9%
Asymmetry	2.1%	N/A
Hypertrophic Scarring	1.7%	1.4%
Skin Rash	1.6%	1.5%
Other Nipple Related Observation	1.5%	1.2%
Ptosis	1.3%	1.3%
Loss of Skin Sensation	1.2%	1.0%
Bruising	1.2%	1.0%
Other Abnormal Scarring	0.9%	0.7%
Redness	0.8%	0.6%
Hematoma	0.8%	0.4%
Other Complications	0.6%	0.4%
Delayed Wound Healing	0.6%	0.4%
Implant Palpability	0.6%	0.4%
Seroma	0.6%	0.4%
Nipple Hypersensitivity	0.4%	0.4%
Nipple Paresthesia	0.4%	0.3%
Fluid Accumulation	0.4%	0.2%
Skin Paresthesia	0.4%	0.3%
Capsule Calcification	0.2%	0.1%
Lymphadenopathy	0.2%	0.1%
Implant Extrusion	0.2%	0.1%
Lymphedema	0.2%	0.1%
Tissue or Skin Necrosis	0.2%	0.1%
Wrinkling/Rippling	0.2%	0.2%
Implant Visibility	0.0%	0.0%
Infection	0.0%	0.0%
Irritation	0.0%	0.0%
Pneumothorax	0.0%	0.0%
Skin Hypersensitivity	0.0%	0.0%

**Table 2. Core Clinical Study – Augmentation Cohort
Summary of Quality of Life Outcome Measures**

	Scale Range	General Population	Baseline	1 Year	Significant
General Health Concepts					
SF36: Role Limitations due to Emotional Problems	0 – 100	79.5	95.7	90.8	↓ *
SF36: Role Limitations due to Physical Health Problems	0 – 100	77.8	96.7	94.4	—
SF36: General Health	0 – 100	70.6	90.9	88.3	↓ *
SF36: Bodily Pain	0 – 100	73.6	91.5	91.8	—
SF36: Social Functioning	0 – 100	81.5	97.4	94.8	↓ *
SF36: Physical Functioning	0 – 100	81.5	98.1	97.6	—
SF36: Vitality	0 – 100	58.4	75.6	70.5	↓ *
SF36: Mental Health	0 – 100	73.3	84.5	82.6	↓ *
SF36: Reported Health Transition	0 – 100	—	36.3	43.0	* ↑
MOS20: Health Perceptions	0 – 100	—	92.4	89.5	↓ *
MOS20: Physical Functioning	0 – 100	—	96.6	95.7	—
MOS20: Role Functioning	0 – 100	—	97.6	96.6	—
MOS20: Social Functioning	0 – 100	—	98.6	97.2	—
MOS20: Mental Health	0 – 100	—	83.1	81.5	↓ *
Specific Self- and Breast-Related Concepts					
Self Concept – Physical Self	18 – 90	—	74.4	75.4	* ↑
Self Esteem	10 – 40	—	36.5	36.2	—
Self vs. Breast Semantic Differential	(-6) – (+6)	—	0.0	0.0	—
Body Esteem – Total Score	32 – 160	—	120.9	123.2	* ↑
Body Esteem – Sexual Attractiveness	13 – 65	—	49.1	52.2	* ↑
Body Esteem – Weight Concern	10 – 50	—	34.8	34.6	—
Body Esteem – Physical Condition	9 – 45	—	37.3	36.5	↓ *
Personal Life Satisfaction	1 – 6	—	4.9	4.8	—
Satisfaction with Breasts	1 – 5	—	1.9	4.5	* ↑
How Well Breasts Matched	1 – 6	—	3.9	5.2	* ↑
Satisfaction with Breast Shape	1 – 5	—	2.4	4.4	* ↑
Satisfaction with Breast Size	1 – 5	—	1.9	4.5	* ↑
Satisfaction with Breast Feel or Touch	1 – 5	—	3.1	4.4	* ↑
Rowland Expectation: Improve Self Image	1 – 5	—	3.0	3.4	* ↑
Rowland Expectation: Improve Social Relations	1 – 5	—	1.2	1.5	* ↑
Rowland Expectation: Improve Daily Living	1 – 5	—	2.6	2.9	* ↑

* Significance is indicated if the overall repeated-measures analysis was significant and the post-hoc comparisons revealed a significant difference between the quality of life scores at baseline and 1 year post-implant.

INTRODUCTION

The McGhan Medical Corporation Silicone-Filled Breast Implant Core Clinical Study is a prospective, 10-year, multi-center clinical study designed to examine the safety and effectiveness of McGhan Silicone-Filled Breast Implants for augmentation, reconstruction, and revision patients. This report presents the results from the augmentation cohort. As this study is still ongoing, this report represents complete 2-year follow-up data, with limited available 3-year safety data included in Appendix D.

METHODS

A. SUBJECTS

1. Patient Enrollment

A total of 495 augmentation patients were enrolled in this study, where enrollment is defined as undergoing implant surgery. The first augmentation patient was enrolled on January 6, 1999, and the last augmentation patient was enrolled on June 30, 2000.

Patients were enrolled in this study if they met the following eligibility criteria:

- Female, age 18 years or older
- Primary breast augmentation (i.e., no previous breast implant surgery) indicated for the following:
  - Patient dissatisfaction with size or shape of breast (e.g., mammary hypoplasia)
  - Asymmetry
  - Ptosis
  - Aplasia
- Adequate tissue available to cover implants
- Patient is willing to follow all study requirements, including agreeing to attend all required follow-up visits, and accepts the risks involved as indicated by signing and dating the study Patient Informed Consent prior to surgery

Patients were not enrolled in the study if they had any of the following characteristics:

- Advanced fibrocystic disease considered to be premalignant without accompanying subcutaneous mastectomy
- Existing carcinoma of the breast, without mastectomy
- Abscess or infection in the body at the time of enrollment
- Pregnant or nursing
- Have any disease, including uncontrolled diabetes (e.g., Hb $A_{1c} > 8\%$), that is clinically known to impact wound healing ability

- Show tissue characteristics that are clinically incompatible with mammaplasty, such as tissue damage resulting from radiation, inadequate tissue, compromised vascularity or ulceration
- Have, or under treatment for, any condition that may constitute an unwarranted surgical risk (e.g., unstable cardiac or pulmonary problems)
- Show psychological characteristics that may be incompatible with the surgical procedure and the prosthesis, such as inappropriate attitude or motivation (e.g., body dysmorphic disorder)
- Are not willing to undergo further surgery for revision, if medically required

One (1) enrolled augmentation patient was later determined to be ineligible and her data was excluded from the analyses. Thus, this report presents data obtained from 494 augmentation patients.

2. Excluded Patients

One (1) augmentation patient was enrolled into the study (i.e., underwent implant surgery), but was subsequently found to be ineligible for study participation. At the time of surgery, this patient was 17 years and 11 months of age, which was under the 18-year age requirement for participation. Thus, this patient's data was excluded from all analyses, although she is still being followed for safety outcomes.

3. Investigators

A total of 20 Principal Investigators (PIs) at 23 sites (defined as a unique PI-IRB combination) enrolled augmentation patients in the Core Clinical Study. Additionally, there are currently 6 other non-implanting Principal Investigators at 7 sites who later joined the study for the purpose of following patients who were originally enrolled by a different physician (e.g., patients who relocated to another state). A number of the 20 implanting investigators had difficulty enrolling the target minimum of 25 augmentation patients indicated in the protocol, primarily due to a less than expected augmentation patient population at these sites. However, 19 of the 20 Principal Investigators did enroll 10 or more augmentation patients each. Only enrolled fewer than 10 augmentation patients (n = 2) despite his efforts in recruiting augmentation patients for the study. A site listing and enrollment distribution is provided in Appendices A-C:

- Appendix A: Investigational Sites by Principal Investigator and Institutional Review Board (IRB)
- Appendix B: Distribution of Patient Enrollment by Implanting Physician
- Appendix C: Distribution of Product Styles by Implanting Physician

B. PROCEDURE FOR DATA COLLECTION

1. Safety Data Collection

Per the study protocol, patients are required to come in for follow-up visits at 0-4 weeks, 6 months, and annually through 10 years post-implant. Additionally, post-implant observations/complications are recorded for patients who come in

for unscheduled visits between scheduled visit intervals. Assessment of safety is based on the occurrence of the following:

a. Unanticipated Adverse Device Effects

An unanticipated adverse device effect is defined on the Unanticipated Adverse Event (UAE) Form as:

> *any serious adverse effect on health or safety or any life-threatening problem or death caused by or associated with the McGhan Mammary Implant or use of the McGhan Mammary Implant, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence, or any other unanticipated serious problem associated with the device that relates to the rights, safety, or welfare of subjects.*

Unanticipated adverse events are captured on an Unanticipated Adverse Event Form. All UAE Forms are reviewed by the Medical Monitor to ascertain if the reported event represents a true UAE or a known medical complication that was incorrectly reported on the UAE Form.

b. Medical Complications

All medical complications are recorded on the Scheduled Follow-Up Visits Form and/or the Complications/Treatment Log Form.

c. Implant Rupture

All implant ruptures are recorded on the Complications/Treatment Log Form, the Explant Form, and/or the MRI Results or Central Reviewer Forms.

d. Reoperations

All reoperations, including the specific types of secondary procedures performed, are captured on a Secondary Surgery Form.

e. Implant Replacement/Removals

Every time an explant is performed, the procedure and details regarding the implant removal are recorded on an Explant Form.

2. Medical History Data Collection

a. Reproduction and Lactation Problems

Reproduction and lactation information was obtained both pre- and post-implant. Pre-implant reproduction and lactation problems are collected on the Medical and Breast Screening History Form. Post-implant reproduction and lactation problems are recorded on the Scheduled Follow-Up Visits Form.

b. Breast Disease

Breast disease information was obtained both pre- and post-implant. Pre-implant breast disease and the results of any pre-implant mammogram within the preceding

year are documented on the Medical and Breast Screening History Form. Post-implant breast disease and the results of any post-implant mammogram are recorded on the Scheduled Follow-Up Visits Form and/or the Complications/Treatment Log Form. Additionally, diagnoses of breast cancer are recorded on the Breast Cancer Form, which collects detailed information regarding the cancer (e.g., tumor size).

c. Connective Tissue/Autoimmune Disease

Pre- and post-implant reports of connective tissue/autoimmune disease are captured on the CTD Confirmation Form. For all patient self-reports of CTD, the investigator attempts to obtain confirmation of the diagnosis from a rheumatologist or attending physician. If the diagnosing physician determines that the patient does not have the CTD she self-reported, then this is recorded as a false report on the CTD Confirmation Form.

Additionally, patients complete an Activities & Lifestyle Questionnaire pre-implant and at 1, 2, 4, 6, 8, and 10 years post-implant. Investigators review each patient's completed questionnaire and refer the patient to a rheumatologist, if necessary, for further evaluation for a possible CTD. If a patient was referred to a rheumatologist and the referral confirmed that the patient had a possible CTD, then a CTD Confirmation Form was completed.

3. Effectiveness Data Collection

Assessment of the effectiveness of McGhan Silicone-Filled Breast Implants is based on the following measures:

a. Changes in Anatomical Configuration

Each augmentation patient's breast/chest dimensions are measured and recorded both prior to implantation (Medical and Breast Screening History Form) and at 6 months and 1 year following implant surgery (Scheduled Follow-Up Visits Form).

b. Satisfaction with Outcome

At each scheduled follow-up visit, both the physician and patient are asked to indicate their satisfaction with the implant surgery on a scale from "definitely dissatisfied" to "definitely satisfied", and to specify any reasons for dissatisfaction. This data is collected on the Scheduled Follow-Up Visits Form.

c. Quality of Life

A variety of quality of life measurements are obtained to target the domains of general health, depression, self-concept and self-esteem, body image, and expectation/satisfaction with breast implant(s). Quality of life information is collected prior to implantation and at 1, 2, 4, 6, 8 and 10 years post-implant. This data is collected on the Quality of Life Form - Pre/Post.

C. GENERAL ANALYSIS APPROACH

1. Overview

Patients from all investigational sites were pooled together for analysis. Inamed believes that the 20 Principal Investigators (representing 25 enrolling sites) participating in the augmentation portion of the Core Clinical Study ensure a good representation of clinical practice and a representative sample of the patient population under study (see Appendices A-C).

2. Analysis of Data Through Two Years

The extract of the database housing the data that was used for the current report was taken on August 30, 2002. For major variables being reported, any known outstanding issues, inconsistencies, or errors were resolved after the final extract using the best available information.

As of the date of the final database extract, all patients have traversed the 2-year follow-up visit interval, and complete 2-year data is available. Thus, the primary analyses presented and discussed in this report are based on the complete 2-year data. Some patients have been seen for their 3-year follow-up visit. However, only 37.9% of augmentation patients have traversed the 3-year follow-up visit interval (those who were at least 2 months past their due date for a 3-year follow-up visit). The 3-year visit interval will not be completed for all patients until August 30, 2003. As a representation of safety beyond 2 years, all post 2-year occurrences of the medical complications listed in Methods Section D.3.b are summarized in Appendix D of this report.

The results of this study are reported by specific post-implant visit intervals (i.e., 0-4 weeks, 6 months, 1 year, 2 years) as well as cumulatively through 2 years. Depending on the data point reported and the type of follow-up information collected, the visit intervals are defined in one of two corresponding ways.

The first approach to data analysis is based on specific follow-up time points defined in terms of number of days post-implant. Complication and reoperation information is collected with the specific date of onset/occurrence recorded. Thus, these outcome variables are analyzed and reported based on the specific follow-up time points in the study and are defined in exact number of days post-implant:

- 0-4 Weeks: 30 days
- 6 Months: 183 days
- 1 Year: 365 days
- 2 Years: 730 days

The primary method of analysis of the complication and reoperation data is survival analysis, using the Kaplan-Meier product limit method, of the time to first occurrence of the particular event under consideration, with time assessed in days post-implant. The "Number Affected" is the number of patients/implants with at least one

occurrence of the event on or before the follow-up time point being reported. The "Number Remaining" is the number of patients/implants without the reported event and who were not lost to follow-up prior to the reported follow-up time point. For each reported follow-up time point, the failure rate is provided along with the associated 95% confidence interval.

The secondary method of analysis of the complication and reoperation data is prevalence and incidence. At each follow-up time point, prevalence is calculated based on all patients/implants who experienced the event, and incidence is calculated based only on the number of new patients/implants who experienced the event since the last follow-up time point. The "Number Evaluated" at each follow-up time point is the number of patients/implants who had a visit during or after the reported follow-up time point. For example, if a patient was seen in the 2-year interval, she is included in the denominator for the 2-year interval, as well as for all previous intervals (e.g., 0-4 weeks, 6 months, and 1 year), even if she did not have a follow-up visit during the previous intervals, because all complications since the last evaluation would be captured at the 2-year visit.

The second approach to data analysis is based on visit windows. These windows are defined in terms of all inclusive, non-overlapping intervals around each follow-up time frame. Reproduction and lactation problems, breast disease, connective tissue/autoimmune disease, and patient satisfaction information were collected at required patient follow-up visits. Additionally, patient compliance is defined based on these same required follow-up visits. These variables are analyzed and reported based on follow-up visit intervals defined as:

- 0-4 Weeks: 0 days through 3 months, 0 days post-implant
- 6 Months: 3 months, 1 day through 9 months, 0 days post-implant
- 1 Year: 9 months, 1 day through 18 months, 0 days post-implant
- 2 Years: 18 months, 1 day through 30 months, 0 days post-implant

Data reported "through 2 years" is inclusive of all results obtained through 30 months post-implant.

3. Analysis of Primary Enrolled Study Implants

This report documents the results obtained for primary enrolled study implants (i.e., original devices implanted). If a primary study implant was removed and replaced with another study device ("secondary" implant), data continues to be gathered on the secondary study implant, adhering to the patient's same ongoing study schedule as for the primary study implant. However, data collected on these secondary implants was not included in the primary analysis, with the exception of patient quality of life and patient satisfaction. Secondary implants were included in the analysis of these latter measures since patients' assessment may be influenced by the occurrence of implant replacement procedures. Outcomes following replacement surgery are presented in a separate report for the revision cohort enrolled in the Core Clinical Study. Appendix

H contains a summary of the medical complications listed in Methods Section D.3.b that occurred following explant and replacement in the augmentation cohort.

If a patient enrolled into the study on one side only (i.e., unilaterally) and later received a study device on the contralateral side, then all by-patient analyses were performed based on the surgery date for the patient's first implant. All by-implant analyses were based on the separate implant surgery dates for each device.

Analyses were conducted using the number of patients and/or the number of implants as the unit of analysis, as appropriate. For example, all demographic data are reported by patient only, whereas data on the type and size of device styles are reported by implant only. Complication rates are reported both by patient and by implant (except for asymmetry, which is reported by patient only).

4. Open-Ended Response Coding

To effectively capture the relevant clinical information recorded in open-ended textual responses on the Case Report Forms (CRFs), specific categories were developed to report these responses. All open-ended responses reviewed were assigned to a category and given a corresponding numeric code that was entered into the clinical database.

A comprehensive approach was used for this coding process. When the grammatical structure of the response was confusing or incomplete, the entire clinical study form and/or patient case history was reviewed and assessed in order to adequately determine which category and code to apply. In some cases the study investigator's office was contacted to clarify the response. Specific coding rules were documented and applied to the overall coding process.

D. METHODS FOR DATA ANALYSIS

1. Patient Enrollment and Surgical Treatment

a. Demographic Variables

For each patient, the following demographic characteristics obtained pre-implant are reported:

- Age
- Race
- Marital Status
- Occupation
- Education
- Height
- Weight

For race and occupation, the sum total of responses may be greater than the total number of enrolled patients due to the fact that all responses are reported, including

multiple responses to the item for the same patient. For patients with more than one educational level provided, the highest indicated level is reported.

The median and range were calculated for patient's age, height, and weight. Patients with missing or invalid data for a variable were not included in the calculation of the median and range for that specific characteristic.

b. Product Styles and Sizes

A frequency distribution of device styles utilized in this study is reported by implant. Additionally, separate frequency distributions by device size are presented for each product style.

c. Primary Surgical Treatment Characteristics

Patients were classified into one of four possible indications for augmentation surgery based on the Primary Surgery Form:

- aplasia
- asymmetry
- ptosis
- dissatisfaction with breast size/shape

If more than one indication was noted for a patient (e.g., both ptosis and aplasia were checked), the patient was classified into one group only based on the hierarchy shown above, giving precedence to the most severe presenting condition.

Anesthesia used for the patient's primary implant surgery was reported as general if general anesthesia was marked on the Primary Surgery Form. Notably, patients reported as sedated through general anesthesia also may have been administered a local anesthetic. If general anesthesia was not checked on the form, then the patient was reported as having been administered a local anesthetic, which may include intravenous sedation.

The type of facility where primary implant surgery occurred, the surgical placement of the device in the breast, and whether drains were placed during primary surgery is reported as documented, based on check boxes on the Primary Surgery Form.

The incision site for implant placement is reported as documented on the Primary Surgery Form. Open-ended responses indicating incision site were coded as described previously. If a check-box incision site was indicated (e.g., axillary) and a mastopexy incision also was noted in the open-ended response, the check-box incision site was used as the incision site for implant placement. If more than one incision site was indicated (excluding mastopexy), the incision site is reported as "Other".

The number of implants with concurrent procedures performed during primary implant surgery is reported. Open-ended responses reporting concurrent procedures

were coded as described previously. All concurrent procedures performed on implanted sides are reported. The sum of all implants across concurrent procedures may be more than the number of implants with concurrent procedures because some implanted sides had more than one type of concurrent procedure performed.

Separate frequency distributions are presented for the number of implants/patients for which intraoperative medication was delivered via pocket irrigation or parenteral medication. Open-ended responses reporting intraoperative medications were coded as described previously. Solutions such as saline or local anesthetic are not reported. The sum total across medications may be greater than the total number of implants/patients with intraoperative medication due to cases where more than one medication was administered to a patient via the same route of administration.

d. Surgical Complications

The number of patients for whom an intraoperative complication was noted is reported. For patients with an intraoperative complication, the specific nature and type of complication is described. To uniquely identify patients in the table, a sequential number starting with 001 was arbitrarily assigned to all patients with an intraoperative complication.

2. Patient Compliance and Discontinuation

Patient compliance at each follow-up visit interval is presented using the visit intervals described previously. "Theoretically Due" refers to patients who were at least 2 months past their due date for a follow-up visit (i.e., patients who should be examined according to their follow-up visit schedule).

Patients became ineligible to be followed up if they:

- Died;
- Had all study devices removed without replacement;
- Had all study devices removed and replaced with non-McGhan devices; or
- Had all study devices removed and replaced with McGhan non-study devices.

The number of "Expected" patients is derived from the difference between those who were theoretically due and those who died or were discontinued due to explantation of all study devices. "Actual Evaluated" during each visit interval is defined as the number of patients who were seen for a scheduled follow-up visit at least once during the interval. "% Follow-Up" is calculated as the number of patients who were evaluated divided by the total number of expected patients for that study interval.

If the patient completes a follow-up visit and also has a discontinuation date within the same visit interval, then the patient is considered compliant for that interval and is considered discontinued in the compliance calculation for the next visit interval. In contrast, if the patient dies or is explanted of all study devices prior to completion of a follow-up visit, then the patient is considered discontinued in the compliance calculation for that visit interval in which her death or explant occurred.

The following measures were taken to minimize the number of patients who were lost to follow-up:

- An active compliance follow-up program was implemented to further remind sites of which patients were due to be seen for required follow-up visits through the use of periodic reminder faxes and phone calls to the Study Coordinators
- Monthly letters were sent to each Investigator providing their site's current percentage of patients seen for the required 2-year follow-up visit
- Monthly letters were sent to each Investigator with a list of patients overdue for their required follow-up visit and asking the Investigator to personally call these patients to schedule their follow-up visit
- Sample letters were provided to sites to send to patients asking the patient to call to schedule her follow-up appointment and to stress the importance of follow-up visits for the study
- A Patient and Investigational Site Incentive Program is included as part of the study protocol
- A Patient Follow-Up Study Coordinator Bonus Program for the 2-year follow-up interval was implemented
- A professional search company was used to locate patients when the site was unable to reach patients at previously known addresses due to relocation
- Patients who relocated were transferred to a new Investigator in their area for follow-up; new Investigators were recruited and enrolled in the study in order to follow patients who moved to areas without an existing Investigator
- Patients who were unable to see an enrolled Investigator during the follow-up interval were able to see another doctor for their required visit (preferably an Investigator participating in a McGhan breast implant study), who would then forward visit notes to the patient's Investigator for completion of the appropriate case report forms

The study sites indicated that non-compliant patients missed their scheduled follow-up visits for a variety of reasons, including: being out of the country, hospitalization for serious illness or injury, being in the military and assigned to active duty, unable to be located, and failure to respond despite repeated contacts made by the site requesting the patient return for a follow-up visit.

The number of patients discontinued through the end of the 2-year visit interval is reported according to one of four primary reasons for discontinuation (see Appendix E for copies of the patient Discontinuation Forms):

- Patient no longer has any McGhan Silicone-Filled Breast Implants
- Patient death
- Patient choice
- Other

Appendix F contains copies of patient Discontinuation Forms for all patients discontinued after the 2-year visit interval.

3. **Safety Assessment**

a. Unanticipated Adverse Device Effects

Unanticipated Adverse Events (UAE) were collected on the Unanticipated Adverse Event Form. The number of UAEs is reported.

b. Medical Complications

Complications were identified from the check-box questions on the Complications / Treatment Log Form. Open-ended responses capturing other complications that were not provided as check boxes on the form were coded as described previously. Complications collected were the following:

- asymmetry
- breast pain
- bruising
- capsule calcification
- capsular contracture
- delayed wound healing
- fluid accumulation
- hematoma
- hypertrophic scarring
- implant extrusion
- implant malposition
- implant palpability
- implant visibility
- infection
- irritation
- loss of nipple sensation
- loss of skin sensation
- lymphadenopathy
- lymphedema
- nipple hypersensitivity
- nipple paresthesia
- other abnormal scarring
- other nipple related observation
- pneumothorax
- ptosis
- redness
- seroma
- skin hypersensitivity
- skin paresthesia
- skin rash

- swelling
- tissue or skin necrosis
- wrinkling/rippling
- other complications

Analyses performed to describe these complications were:

- Cumulative risk (Kaplan-Meier)
- Prevalence
- Incidence
- Method of resolution
- Duration (time to resolution)

For the implant extrusion and pneumothorax complications, all reported occurrences are included in the analysis regardless of the severity rating provided by the physician (i.e., very mild, mild, moderate, severe, or very severe). As determined in consultation with Inamed's Medical Advisor, Dr. Scott Spear, for all other complications, only reported occurrences that were in the moderate, severe, or very severe range are included in the analysis (for capsular contracture, Baker Grades III and IV were included in the analysis). Very mild and mild indications of these events (for capsular contracture, Baker Grades I and II) are not considered clinical problems; rather, these occurrences are within the range of what is considered normal for women with implant surgery. This method for reporting complications is identical to the approach used in the McGhan Medical PMA submission for saline-filled breast implants (PMA #P990074, approved May 10, 2000). For completeness, a distribution of all severity levels for each complication also is provided, including very mild and mild occurrences (for capsular contracture, Baker Grades I and II).

For comparison purposes, the 2-year risk rates observed in this study are discussed relative to the 2-year risk rates observed in the 1995 Saline Augmentation Clinical Study.

The method of risk analysis used for this report is not subject to the problem of competing risks (FDA/McGhan Teleconference, March 17, 2000) because once a patient experiences her first complication (e.g., breast pain at 15 days post-implant) she is not removed from the pool of patients who may experience (and be reported as having) another complication (e.g., capsular contracture at 45 days post-implant).

The analysis of method of resolution for each complication was conducted on a by-patient basis. The following resolution hierarchy was used:

- Undergoing treatment
- Treatment not possible
- Refused treatment
- Resolved with treatment
  - Reoperation with explantation

  - Reoperation without explantation
  - Non-surgical treament
- Resolved without treatment

Although a patient may have undergone multiple treatments for a particular complication, the treatment that actually resulted in resolution of the complication is reported. Additionally, patients may concurrently undergo one type of treatment to resolve one complication and a different type of treatment to resolve a second complication. For example, a patient experiencing both capsular contracture and a skin rash may be explanted due to capsular contracture. The reoperation with explantation resolves the capsular contracture; however, the skin rash is resolved several months later with topical cream, a non-surgical treatment. Patients are categorized as "Resolved with Treatment" via reoperation if the physician marked "Resolved with Treatment" on the Complications/Treatment Log Form and a Secondary Surgery Form was completed for a reoperation occurring 0-30 days prior to the resolution date of the complication for the purpose of treating that type of complication. Further, these patients are divided into one of the two reoperation categories: reoperation with explantation (an Explant Form was completed) and reoperation without explantation. If a patient experienced the same complication on both breasts, then the breast with the worst-case method of resolution (higher in the hierarchy) was used in the analysis.

Duration (time to resolution) of the complication was also analyzed on a by-patient basis. If a patient experienced the same complication on both breasts, then the breast with the longest duration of time to resolution was used for analysis. Time to resolution was derived from the difference between the date of resolution and the date of onset for the complication. If the complication was resolved the same day as the day of onset, then time to resolution is reported as 1 day. If the complication was not resolved, then the elapsed treatment time was calculated as the difference between the date of onset and the last date the patient was seen by her physician (i.e., completion of Scheduled Follow-Up Visits Form and/or the Complications/Treatment Log Form).

c. Implant Rupture

Implant rupture was identified from three sources:

- the check-box "suspected rupture" question on the Complications / Treatment Log Form
- evidence of rupture observed by the physician upon reoperation or device explant (Explant Form)
- devices identified as ruptured or indeterminate for rupture via MRI (MRI Results and Central Reviewer Forms), for those patients participating in the serial MRI portion of this study (a separate report detailing the results of patients' 1st serial MRI is included in this PMA submission)

All devices are categorized according to whether rupture was suspected. If implant rupture was identified, the specific method used to identify the rupture is reported:

explant, MRI, reoperation, mammography, ultrasound, or physician exam. If rupture was identified by physician exam, the specific physical symptoms of rupture are presented.

For each suspected rupture, the Investigator determined the appropriate follow-up treatment with the patient (e.g., explantation, additional diagnostic testing, no treatment). Based on the results of this follow-up, all suspected ruptures were classified into one of the following three categories:

- Confirmed rupture via explant
- False report: device intact
  - Explant indicated no rupture
  - Mammography indicated no rupture
  - Ultrasound indicated no rupture
  - MRI indicated no rupture
- Unconfirmed rupture

Ruptures determined to be false reports based upon additional Investigator follow-up are not included in the analyses for implant rupture.

The onset date provided for symptomatic ruptures identified by the physician is used in the analysis. For ruptures identified via reoperation/explant or diagnostic testing (i.e., asymptomatic or silent ruptures), the exact date of occurrence of the rupture is unknown. Thus, the onset time for silent rupture was estimated as halfway back from the date of the patient's reoperation/explant or diagnostic test to the last date the implant was known to be intact (i.e., date of implantation). For example, if a patient had her 1st serial MRI performed after her 2-year follow-up visit (e.g., at 800 days post-implant) where evidence of rupture was noted, then the estimated date of onset of silent rupture would be recorded as 400 days post-implant.

Analyses performed to describe implant rupture were:

- Cumulative risk (Kaplan-Meier)
- Prevalence
- Incidence
- Method of resolution

d. Reoperations

A "reoperation" is defined as a visit during which at least one secondary procedure was performed involving one or more primary study devices. Each patient may have more than one reoperation, and more than one secondary procedure may be performed during each reoperation. Analyses describing reoperations are:

- Cumulative risk (Kaplan-Meier)
- Number of reoperations per patient

- Intraoperative complications during reoperation
- Primary reason for reoperation
- Primary procedure performed
- Number of procedures performed per reoperation
- Types of procedures performed during reoperation

The number of intraoperative complications occurring during reoperation is reported. For reoperations where an intraoperative complication was indicated, a description of the complication is provided in the table. In order to uniquely identify patients in the table, a sequential number starting with 001 was arbitrarily assigned to all patients with an intraoperative complication.

Open-ended responses reporting other reasons for reoperation (i.e., reasons not included in the check boxes on the Secondary Surgery Form and Explant Form) and other procedures performed (i.e., procedures not included in the check boxes on the Secondary Surgery Form) were coded as described previously.

If more than one reason for reoperation was identified, then the primary reason was reported based on the following hierarchy:

- Device Malfunction – Rupture
- Injury – Iatrogenic or Traumatic
- Breast Cancer
- Capsular Contracture
- Infection
- Healing Related
  - Extrusion
  - Necrosis
  - Hematoma/Seroma
  - Delayed Wound Healing
  - Nipple Complications
- Pain
- Unsatisfactory Cosmetic Result
  - Breast Tissue Contour Deformity
  - Malposition
  - Wrinkling/Rippling
  - Implant Palpability/Visibility
  - Asymmetry
  - Ptosis
  - Scarring
- Patient Request
  - Style/Size Change
  - Media Anxiety
- Need for Biopsy
- Other

This hierarchy was derived using FDA's Guidance Document "*Guidance for Saline, Silicone Gel, and Alternative Breast Implants; Final Guidance for Industry*". The following reasons, which were not included in FDA's guidance document, were added to the hierarchy used in order to be comprehensive of all reasons for reoperation reported: Injury – Iatrogenic or Traumatic, Breast Cancer, Delayed Wound Healing, Nipple Complications, Implant Palpability/Visibility, Ptosis, Breast Tissue Contour Deformity, Need for Biopsy, and Media Anxiety.

At each reoperation, a patient/implant may have more than one procedure performed. If more than one procedure was performed, then the primary procedure for each reoperation was reported based on the following hierarchy:

- Implant Removal
  - With Replacement
  - Without Replacement
- Capsule Procedure
  - Capsulotomy
  - Capsulorraphy
  - Capsulectomy
- Flap Procedure
- Pocket Revision
- Reposition Implant
- Surgical Exploration of Breast Area or Implant
- Mastopexy
- Breast Reduction
- Wound Repair
- Aspiration of Hematoma/Seroma
- Liposuction
- Removal of Excess Tissue/Lesion/Cyst
- Revision of Nipple Reconstruction/Tattoo
- Scar Revision
- Biopsy
- Other

If both a capsule procedure and a reposition implant procedure were performed together during a single reoperation, the capsule procedure is reported only if capsular contracture was specifically stated as a reason for the reoperation; otherwise, only reposition implant is reported, because a capsule procedure was necessary in order to reposition the implant. If both implant removal without replacement and a capsule or flap procedure were performed together during a single reoperation, then only implant removal is reported, because the capsule or flap procedure was necessary to remove the implant.

e. Implant Replacement/Removal

Kaplan-Meier analysis is conducted on the time to first occurrence of implant replacement/removal both by patient and by implant. Additionally, separate risk analyses are performed on the time to first occurrence of implant removal with replacement and implant removal without replacement.

A frequency distribution of the primary reasons for implant replacement/removal is provided. If more than one reason was indicated for an explanted side, the primary reason for explant was identified based on the primary reason for reoperation hierarchy described in Methods Section D.3.d.

For implants that were replaced, the types of replacement devices inserted after removal of the primary enrolled study device are reported. Each replacement device was classified as follows:

- a McGhan study device
- other McGhan device (non-study)
- non-McGhan device
- unknown replacement device type

The size of the replacement device relative to the primary enrolled study device is presented for those implants replaced with another McGhan study device (where the size of the replacement device was known). Replacement devices were categorized according to whether they were larger, smaller, or the same size as the original study device.

Finally, the physician's evaluation of each explanted device is presented for ruptured and non-ruptured (intact) devices. The physician's evaluations of the following four device characteristics are presented: capsule torn (not intact), extracapsular gel, gel on implant surface, and difficulty removing the device.

f. Risk of Any Complication

The risk of any complication is presented in three separate analyses, which group the 34 medical complications, implant rupture, and reasons for reoperation/replacement/removal into three distinct categories based on the type of complication: general breast surgery, breast implant surgery – cosmetic, or breast implant surgery – non-cosmetic.

i. General Breast Surgery Complications

General breast surgery complications were defined as complications, which are related to breast surgery or resulting from surgery in general. The specific events included in the general breast surgery complication category were:

- Breast Pain
- Bruising

- Delayed Wound Healing
- Fluid Accumulation
- Hematoma
- Hypertrophic Scarring
- Infection
- Irritation
- Lymphadenopathy
- Lymphedema
- Loss of Nipple Sensation
- Loss of Skin Sensation
- Nipple Hypersensitivity
- Nipple Paresthesia
- Other Abnormal Scarring
- Other Complications
- Other Nipple Related Observation
- Pneumothorax
- Ptosis
- Redness
- Seroma
- Skin Hypersensitivity
- Skin Paresthesia
- Skin Rash
- Swelling
- Tissue or Skin Necrosis
- Reoperation/Replacement/Removal for:
    - Breast Cancer
    - Breast Tissue Contour Deformity
    - Delayed Wound Healing
    - Hematoma/Seroma
    - Infection
    - Injury – Iatrogenic or Traumatic
    - Necrosis
    - Need for Biopsy
    - Nipple Complications
    - Other
    - Pain
    - Ptosis
    - Unsatisfactory Scar

ii. Breast Implant Surgery – Cosmetic Complications

Breast implant surgery – cosmetic complications were defined as complications resulting from the breast implant surgery, which are related to the cosmetic

appearance of the breast and are not considered medical complications. The specific events included in the breast implant surgery – cosmetic complication category were:

- Asymmetry
- Implant Malposition
- Implant Palpability
- Implant Visibility
- Wrinkling/Rippling
- Reoperation/Replacement/Removal for:
    - Malposition
    - Wrinkling
    - Implant Palpability/Visibility
    - Asymmetry
    - Patient Request (Style/Size Change)

iii. Breast Implant Surgery – Non-Cosmetic Complications

Breast implant surgery – non-cosmetic complications were defined as complications resulting from the breast implant surgery which are not considered strictly cosmetic in nature. The specific events included in the breast implant surgery – non-cosmetic complication category were:

- Capsule Calcification
- Capsular Contracture
- Implant Extrusion
- Implant Rupture
- Reoperation/Replacement/Removal for:
    - Capsular Contracture
    - Device Malfunction – Rupture
    - Extrusion
    - Patient Request (Media Anxiety)

4. Medical History

Unlike specific medical complications such as implant extrusion, capsular contracture, and wrinkling/rippling, there is no valid scientific evidence to suggest that breast implants are causally associated with systemic conditions such as breast cancer or connective tissue/autoimmune diseases (Bondurant, 2000). As such, the frequency of occurrence is used to report reproduction and lactation problems, breast cancer and benign breast disease, and connective tissue/autoimmune disease, rather than the cumulative risk used to report medical complications.

a. Reproduction and Lactation Problems

The number of patients who reported reproduction or lactation problems is presented separately for pre-implant and post-implant reports. The total number of reproduction

or lactation problems could exceed the number of patients who experienced problems due to the fact that patients could have more than one reproduction or lactation problem. Open-ended responses indicating reproduction or lactation problems were coded as described previously. The number of patients who had both pre- and post-implant reproduction or lactation problems also is provided.

b. Breast Cancer and Benign Breast Disease

The number of patients with a pre-implant and/or post-implant occurrence of breast cancer or benign breast disease is reported. To identify patients with pre-implant breast disease, the Medical and Breast Screening History Form and the Breast Cancer Form were used. To identify patients with post-implant breast disease, the Breast Cancer Form, Complications/Treatment Log Form, and Scheduled Follow-Up Visits Form were examined. Patients with a reported breast disease were classified based on the following hierarchy:

- Confirmed Malignant Disease
- Unconfirmed Malignant Disease
- Benign Disease (including Fibrocystic Disease)
- Unknown Breast Disease

Results of pre-implant and post-implant mammograms (i.e., abnormal vs. normal mammogram results) are reported for all patients. For any abnormal mammogram result, the patient's breast disease status is provided using the same hierarchy described above.

c. Connective Tissue/Autoimmune Disease

The number of patients who reported a connective tissue/autoimmune disease (CTD) is presented separately for pre-implant reports and post-implant reports. All patient self-reports of a CTD were recorded on the CTD Confirmation Form. For each self-report, the Investigator attempted to obtain confirmation of the patient's self-reported CTD from a diagnosing physician. Based on the results of this follow-up, all patient self-reported CTDs were classified into one of the following 3 categories:

- Confirmed CTD (a diagnosing physician confirmed the CTD self-reported by the patient)
- Unconfirmed CTD (confirmation from a diagnosing physician was not able to be obtained; e.g., the patient did not visit a rheumatologist for further evaluation)
- False Report (a diagnosing physician indicated that the patient does not have the CTD the patient self-reported)

5. Effectiveness Assessment

a. Changes in Anatomical Configuration

Changes in anatomical configuration were measured by bra size change and by a change in the patient's lateral breast measurement. Both measures were assessed pre-

implant and at the 6 month and 1 year post-implant visits. Only patients with both a valid pre- and post-implant measure were included in the analysis.

A valid bra size was defined as an even number of inches from 30-46 and one of the following cup sizes:

- AA
- A
- B
- C
- D
- DD
- E
- F

If the patient's bra size measurement (inches or cup) fell between two valid measurements (e.g., 33 inches was reported), the measurement was converted to the next highest valid measurement (e.g., 34 inches).

The lateral breast measurement was defined as the distance from the point at which the breast mound begins laterally across the nipple to where it ends medially. A valid breast measurement was defined as a measurement number between 1cm and 60cm.

Because breast measures (bra size and lateral breast measurement) could be provided both at the 6 month and 1 year post-implant visits, the first valid post-implant measure observed between one month and 18 months after implant surgery was used. This time frame was chosen because prior to one month the patient could still be experiencing swelling of the breasts and settling of the implants following surgery. After 18 months post-implant, breast size is more likely to be affected by other factors besides breast implantation, such as weight gain or loss. If the patient had a post-implant pregnancy that occurred on or before the time her first valid post-implant breast measure was recorded, then her data was excluded because of the potential effect of the pregnancy on breast size.

Three types of analyses were performed to assess changes in anatomical configuration. First, the change in bra cup size pre- vs. post-implant was assessed.

Second, valid bra sizes were converted to a numerical scale to allow a more direct comparison of the change between pre- and post-implant bra sizes. Each valid bra size (inches and cup) was translated into a numerical scale score from 1 to 13, with each one step increase in bra inches (e.g., 34 to 36) or cup size (e.g., B to C) resulting in a one point increase on the scale. For example, the lowest scale score (1) was assigned to the smallest possible bra size "30AA". A "32AA" was assigned a scale score of 2, as was a "30A"; a "32A" was assigned a scale score of 3, and so forth. A paired t-test was conducted on the difference between patients' pre- and post-implant bra size scores.

Third, a paired t-test was conducted on the difference between patients' pre- and post-implant lateral breast measurements.

b. Satisfaction with Outcome

Frequency distributions of the degree of patient and physician satisfaction regarding the breast implantation are presented for each study visit interval. If more than one assessment is reported by the patient or physician during a visit interval, the worst-case (more dissatisfied) assessment indicated is reported. The total number of patients included in the analysis for any visit interval may be less than the total number of patients seen during that interval (as indicated in the compliance table) due to patients who were seen for a follow-up visit but for whom no assessment of their implants was made during the visit.

A frequency distribution of the specific dissatisfactions expressed by physicians and patients is provided. Some dissatisfaction reasons were specified even though the physician/patient did not indicate being dissatisfied in the forced choice rating scale. Open-ended responses reporting dissatisfaction by patients and physicians were coded as described previously into one of four categories:

- Aesthetic: dissatisfaction related to the aesthetic outcome of the surgery
- Implant Design: any comment regarding the design of the implant (e.g., thicker)
- Medical/Procedural: dissatisfaction related to the medical or procedural outcome of the surgery
- Other

Additionally, a frequency distribution of the degree of patient satisfaction regarding the breast implantation is presented for each study interval, including patients with both primary and secondary study devices (i.e., those who underwent device removal and replacement with another McGhan study device during the course of the study).

c. Quality of Life

A repeated-measures design, with a pre-surgical baseline measurement and periodic reassessments post-implant, was used to assess the effect of breast implants on different domains of quality of life. Given that no quality of life instruments exist specifically for use with breast implant recipients, patients were asked to answer multiple validated and non-validated scales. The scales are described below.

Quality of life analyses were conducted including patients with both primary and secondary study devices (i.e., those who underwent device removal and replacement during the course of the study).

i. General Health

Portions of two widely used surveys were employed to measure general health: The Medical Outcomes Study (MOS) 20-Item Health Survey (Ware et al., 1993) and the SF-36 Status Survey (Stewart, 1988). Both surveys measure generic quality of life outcomes (i.e., mental health and bodily pain) and were developed from the surveys used in the Medical Outcomes Study, an observational study of variations in physician practice style and patient outcomes in different systems of care (Stewart, 1988; Ware et al., 1993).

Data from the following MOS-20 scales are collected and analyzed in the current study:

- health perceptions
- physical functioning
- role functioning
- social functioning
- mental health

Data from the following SF-36 scales are collected and analyzed in the current study:

- role limitations due to emotional problems
- role limitations due to physical health problems
- general health
- bodily pain
- social functioning
- physical functioning
- vitality
- mental health
- reported health transition

As data is available for the SF-36 scales from the general U.S. female population, a comparison to the results obtained from this study population was conducted.

ii. Depression Screen

Three depression screening questions were used to assess the presence of chronic depression in the study population (Burnam et al., 1988).

iii. Self-Concept and Self-Esteem

A portion of the Tennessee Self-Concept Scale (TSCS), a widely used and validated instrument (Fitts, 1989), was incorporated into the quality of life assessment for this study. Specifically, the TSCS Physical Self Scale was utilized and contains 18 items that are scored on a 5-point scale ranging from "completely true" to "completely false". This scale reflects the respondent's view of her body and state of health, as well as her attitude about appearance, skills, and sexuality.

Since self-concept was relatively broad, the Rosenberg Scale, which focuses specifically on self-esteem, was included in the quality of life questionnaire in an attempt to increase sensitivity to detecting the quality of life outcomes that result from breast implantation. The Rosenberg Scale is a 10-item scale that measures the respondent's feelings concerning self-worth and self-acceptance. Respondents were asked to what extent they agreed or disagreed with each of ten statements concerning self-esteem. The four possible responses range from "strongly disagree" to "strongly agree". The Rosenberg Scale has been widely used and is frequently the standard by which developers of other self-esteem measures seek convergence (Rosenberg, 1965).

iv. Body Image

The Body Esteem Scale is used to measure one's degree of satisfaction or dissatisfaction with the various parts or processes of the body (Franzoi et al., 1984). The Body Esteem Scale contains 32 items that are scored on a 5-point scale ranging from 1 (have strong negative feelings) to 5 (have strong positive feelings). The subscales within this measure (for females) are sexual attractiveness, weight concern, and physical condition.

In addition, based on the Semantic Differential Test (Osgood, 1952), measures of body image specific to "my breasts" and to "myself" were included in this quality of life instrument. The Semantic Differential Test consists of pairs of bipolar terms divided by a continuum. The respondent is asked to check the point on each continuum that best reflects his/her feelings. Originated in 1952, the Semantic Differential Test attempts to measure the way a respondent feels by relating feelings to certain words representative of the positive or negative (Osgood, 1952). In this study, the Semantic Differential Test was used to determine whether augmentation mammoplasty promotes congruence between body-part and overall self-image.

v. Motivations

Included in the baseline quality of life questionnaire was a listing of possible motivations for implant surgery. Patients were asked to rate their motivations for undergoing breast augmentation according to importance.

vi. Expectation and Satisfaction

Several measures were included to assess patients' pre-implant expectation and post-implant satisfaction with their breast implants. First patients were asked at baseline how satisfied they expected to be with their breast implants. At follow-up, a parallel question was asked to measure patients' actual satisfaction with their implants. Possible responses to these questions range from "very dissatisfied" to "very satisfied".

Second, a 16-item scale developed to measure expectation and perceived results of breast implant surgery among reconstruction patients was used (Rowland, 1984). Thirteen (13) of the items were relevant for all types of breast implant patients and assess general quality of life outcomes (e.g., made me feel more attractive, made me feel more self-confident), whereas 3 of the items are relevant only for reconstruction patients and assess outcomes specific to breast reconstruction surgery (e.g., helped me feel less conscious of having had breast cancer, helped me hide the mastectomy better). The augmentation patients answered the 13 generalized items, which comprise the following 3 scales:

- Improve Self Image
- Improve Social Relations
- Improve Daily Living

The subscale Improve Well-Being was not measured among the augmentation patients because this subscale contains questions specific only to the reconstruction population.

Finally, several other satisfaction questions were included in the quality of life instrument that pertain to the patient's satisfaction with her personal life and breasts. The questions that ask specifically about satisfaction with different aspects of the breast (e.g., shape, size, and feel of breasts) were included in order to provide insight on how successful the surgery was, based on the patient's perspective and independent of her expectations.

vii. Worry

Two questions were included to elicit information concerning the amount of worry a patient has concerning her implants. These questions were asked of the patient only at post-implant.

viii.Pain and Problems with Work/Activities

One question was included to measure the amount of bodily pain a patient attributes to her implants. This question was asked only post-implant with response choices ranging from "not at all" to "extremely".

One question was included to record, in the past 4 weeks, to what extent the patient had problems in performing her work or activities due to her implants.

ix. Scoring and Analysis

Each quality of life scale was scored independently with only the items that were included in that scale.

Change in quality of life scores pre- vs. post-implant was examined to provide information regarding the effect of breast augmentation with McGhan Silicone-Filled Breast Implants on patients' quality of life. Repeated-measures analyses were employed to measure change.

Two different types of repeated-measures analyses were conducted:

- For scales involving interval-level data where means were computed, a repeated-measures ANOVA was conducted. If the overall repeated-measures analysis was significant, post-hoc comparisons using Tukey's multiple comparison technique were conducted to determine which specific means differed. The Type III partial sum of squares p-value was reported.
- For items with a dichotomous response (e.g., YES/NO), a Cochran-Mantel-Haenszel General Association Statistic was computed with Scheffé's correction for multiple comparisons.

A patient was included in a particular repeated-measures analysis if a score was provided at all relevant time points. If a patient was missing an observation at any of the time points used in the analysis, then she was omitted from the analysis because repeated-measures analysis with missing data is not recommended (Walker, 1997). Also, if more than 50% of items in a scale are missing, then the scale score is not calculated and left missing.

As indicated in FDA's Guidance Document "*Guidance for Saline, Silicone Gel, and Alternative Breast Implants; Final Guidance for Industry*", it is important to adjust the Type I error rate when multiple hypothesis tests are conducted. For the quality of life analyses, the Type I error rate was adjusted using a Bonferroni correction (Godfrey, 1992). Specifically, for measures that contained multiple subscales (e.g., SF-36) the overall probability of committing a Type I error for the instrument was set at 0.05, with the alpha divided equally for each subscale tested. That is, the individual alpha level for each subscale was equal to 0.05 divided by the total number of subscales (i.e., the number of tests performed). If the measure also had an overall scale score that was analyzed, then the alpha was set at 0.05 for the overall test but the alpha was adjusted for the multiple subscales tested.

When significant results were obtained, effect sizes were calculated to identify clinically meaningful changes in quality of life scores. The effect size was calculated by dividing the difference between the pre-implant mean and the 1-year post-implant mean by the pre-implant standard deviation (Kazis et al., 1989). Small effect sizes (i.e., < 0.20) indicate little, if any, clinically meaningful change in health-related quality of life. Cohen (1988) describes a moderate effect size as 0.50 and a large effect size as 0.80.

Finally, an independent samples t-test was conducted to compare baseline quality of life scores with similar scale scores obtained from the general U.S. female population for the SF-36 scales.

6. Risk Factor Analysis

As suggested in FDA's Guidance Document "*Guidance for Saline, Silicone Gel, and Alternative Breast Implants; Final Guidance for Industry*", an analysis was conducted to examine whether specific patient, device, and surgical characteristics are risk factors associated with clinical outcomes. The following five critical clinical outcomes were examined:

- reoperation
- implant replacement/removal
- implant rupture
- capsular contracture
- infection

The following 7 patient, device, and surgical characteristics, suggested in FDA's Guidance Document, were selected as potential risk factors:

- patient age (<=40 vs. >40) (Table 1)
- pocket irrigation-antibiotic (yes vs. no) (Table 16)
- pocket irrigation-betadine (yes vs. no) (Table 16)
- implant placement (submuscular vs. other) (Table 13)
- incision site (periareolar vs. inframammary vs. axillary vs. other) (Table 12)
- device texture (smooth vs. textured) (Table 4)
- device shape (round vs. shaped) (Table 4)

A Cox proportional hazards regression analysis was performed by implant for each of the five outcome variables to identify any significant risk factors. Both univariate and multivariable techniques were used. First, univariate models were fit for each potential risk factor. The potential risk factors that resulted in a significance of $p< .25$ from the univariate models were then entered into a multivariate model (Hosmer et al., 2000). The multivariate model was derived using the backward elimination model building technique with $p<.01$ for stay criteria. The significance level of 0.05 was adjusted to 0.01 for each of the 5 multivariate models using a Bonferroni correction (Godfrey, 1992), with the alpha divided equally for each of the 5 outcomes.

For each clinical outcome, the characteristics that were found to be statistically significant risk factors in the multivariate model are reported. For each outcome, two tables are used to present the risk factor analysis results. The first table presents the frequency of the outcome for each level of the risk factors that were significant (e.g., 6.3% of smooth devices underwent implant replacement/removal vs. 1.6% of textured devices). The second table presents the unadjusted risk ratio for each risk factor as well as the adjusted risk ratio and associated 95% confidence interval. The

unadjusted risk ratio is calculated as the ratio of the percentage of devices with the outcome for the two levels of the characteristic. The adjusted risk ratio is from the multivariate model and adjusts for the other significant factors in the model.

RESULTS

A. PATIENT ENROLLMENT AND SURGICAL TREATMENT

1. Demographic Characteristics

Tables 1 – 3

Patients' pre-implant demographic characteristics are presented in Tables 1-3.

As reported in Table 1, the median patient age was 34 years, with a range from 18 to 60 years. Most patients were Caucasian (84.0%); several patients indicated more than one race, yielding a total percentage greater than 100%. Nearly half of patients (48.6%) were married.

Table 2 reports occupation and education data for the augmentation patients. Half of the patients (50.2%) were employed in professional jobs. The vast majority of patients (84.2%) had at least some college education.

As reported in Table 3, patients' median height was 5'5", with a range of 4'10" to 6'0", and their median weight was 125 pounds, with a range of 90 to 200 pounds.

The demographic profile obtained for the augmentation patients enrolled in this Core Clinical Study is comparable to the demographic characteristics of the augmentation patients enrolled in Inamed's 1995 Saline Augmentation Clinical Study (A95). In the A95 Saline Study, patients' median age was 32 years, 88.0% were Caucasian, 52.3% were married, 37.4% were employed in professional jobs, 76.1% had at least some college education, patients' median height was 5'5", and patients' median weight was 123 lbs. The demographic profile for the augmentation patients enrolled in this Core Silicone Study also is consistent with data on patients who undergo plastic surgery reported by the American Society for Aesthetic Plastic Surgery (2001), which showed that the majority of breast augmentation patients are between 19-50 years old, and the majority of patients who undergo cosmetic procedures are Caucasian.

2. Product Styles and Sizes

Tables 4 – 9

Table 4 presents a distribution of the device styles used for the augmentation patients in this study. Nine hundred and eighty-seven (987) primary study devices were implanted in the 494 augmentation patients. Round device styles were more commonly used (92.4%) than were shaped styles (7.6%). A fairly equal distribution of smooth vs. textured devices were used (54.7% vs. 45.3%).

Tables 5-9 present a distribution of the device sizes implanted for each product style.

3. Surgical Treatment Characteristics

Tables 10 – 17

Table 10 presents a distribution of the indications for breast augmentation surgery. The majority of patients (67.8%) who enrolled in this study did so strictly for cosmetic augmentation (i.e., dissatisfaction with breast size/shape). The remaining patients enrolled for cosmetic augmentation with accompanying conditions as follows:

- 76 patients (15.4%): breast ptosis
- 61 patients (12.3%): asymmetry
- 22 patients (4.5%) : aplasia

Tables 11-17 describe the characteristics of patients' primary implant surgery.

Most patients were administered a general anesthetic (75.9%), with the remaining patients anesthetized solely using a local anesthetic (24.1%), (Table 11).

Nearly half of augmentation patient surgeries (47.6%) were performed in a doctor's office and more than one third (39.7%) were performed in a free standing surgical facility (Table 11). Relatively few augmentation surgeries were performed in a hospital (12.8%),

The most common incision sites for implant placement were inframammary (46.8%) and periareolar (39.3%), (Table 12).

The majority of devices were placed submuscularly (68.3%) or subglandularly (31.1%), (Table 13).

The vast majority of devices were inserted without the use of drains (81.4%), (Table 14).

Concurrent breast procedures were performed for 146 (14.8%) of the 987 device surgeries. A total of 154 concurrent procedures were performed during the 146 device surgeries, most commonly mastopexy (87.7%), (Table 15). The sum across concurrent procedures is greater than 100% because some device surgeries involved more than one concurrent procedure.

The majority of the 987 device surgeries (92.3%) involved administration of some type of medication through pocket irrigation (Table 16). The medications used most frequently during device surgeries were antibiotics (83.5%) and betadine (43.5%). The sum across intraoperative medications administered through pocket irrigation is greater than 100% because some implant surgeries involved administration of more than one type of medication via this route

The majority of the 494 patients (86.4%) were administered parenteral medication, most commonly antibiotics (99.3%), (Table 17). The sum across parenteral medications is

greater than 100% because some patients were administered more than one type of medication by this route.

4. Surgical Complications

Table 18

No intraoperative complications were reported during primary implant surgery for any of the 987 implanted devices in the 494 patients (Table 18).

B. PATIENT COMPLIANCE AND DISCONTINUATION

Four hundred and ninety-three (493) of the 494 enrolled patients (99.8%) were evaluated during at least one post-operative follow-up visit through 2 years.

Accounting for those patients who were discontinued due to death or explant of all study devices, compliance was 85.7% at the 1-year follow-up visit and 89.8% at the 2-year follow-up visit (Table 19). No augmentation patients died during the period of this report.

Based on data obtained through 2 years, 10 of the 494 augmentation patients (2.0%) were discontinued from the study (Table 20). Of these 10 discontinuations, 8 were due to removal of all study devices and 2 were due to patient choice to discontinue from the study.

C. SAFETY ASSESSMENT

1. Unanticipated Adverse Events

No Unanticipated Adverse Event Forms have been received for augmentation patients. There have been no Unanticipated Adverse Events (UAEs) associated with McGhan Silicone-Filled Breast Implants for any augmentation patients.

2. Medical Complications

Tables 21 – 157

Tables 21-156 present the following results for each of the medical complications assessed in this study:

- Kaplan-Meier risk analysis
- Prevalence and incidence analysis
- Duration of complication
- Method of resolution

For example, analyses are presented for asymmetry in Tables 21-24. Table 21 shows the risk of first occurrence of asymmetry using Kaplan-Meier analysis. Table 22 reports the incidence and prevalence of asymmetry during each study interval. Table 23 presents the

time to resolution of asymmetry. Table 24 shows the distribution of resolution status for asymmetry.

The following table summarizes the 2-year risk rates and associated 95% confidence intervals for each complication, both by patient and by implant. Complications are sorted from the highest to the lowest 2-year risk rates by patient. The risks reported in this table are not additive because a patient may experience more than one complication and would be included in the risk for each complication.

Complication	(Table #)	2-Year Risk By Patient % (95% CI)	2-Year Risk By Implant % (95% CI)
Swelling	(141)	6.8% (4.5%, 9.0%)	5.6% (4.2%, 7.1%)
Capsular Contracture	(37)	6.7% (4.5%, 9.0%)	5.1% (3.7%, 6.5%)
Breast Pain	(25)	5.0% (3.0%, 6.9%)	3.3% (2.2%, 4.4%)
Loss of Nipple Sensation	(81)	3.1% (1.6%, 4.7%)	2.4% (1.4%, 3.4%)
Implant Malposition	(61)	2.5% (1.1%, 4.0%)	1.9% (1.0%, 2.8%)
Asymmetry	(21)	2.1% (0.8%, 3.4%)	N/A
Hypertrophic Scarring	(53)	1.7% (0.5%, 2.8%)	1.4% (0.6%, 2.1%)
Skin Rash	(137)	1.6% (0.5%, 2.8%)	1.5% (0.8%, 2.3%)
Other Nipple Related Observation	(109)	1.5% (0.4%, 2.6%)	1.2% (0.5%, 1.8%)
Ptosis	(117)	1.3% (0.3%, 2.4%)	1.3% (0.6%, 2.1%)
Loss of Skin Sensation	(85)	1.2% (0.3%, 2.2%)	1.0% (0.4%, 1.7%)
Bruising	(29)	1.2% (0.3%, 2.2%)	1.0% (0.4%, 1.7%)
Other Abnormal Scarring	(105)	0.9% (0.0%, 1.8%)	0.7% (0.1%, 1.2%)
Redness	(121)	0.8% (0.0%, 1.6%)	0.6% (0.1%, 1.1%)
Hematoma	(49)	0.8% (0.0%, 1.6%)	0.4% (0.0%, 0.8%)
Other Complications	(153)	0.6% (0.0%, 1.4%)	0.4% (0.0%, 0.8%)
Delayed Wound Healing	(41)	0.6% (0.0%, 1.3%)	0.4% (0.0%, 0.8%)
Implant Palpability	(65)	0.6% (0.0%, 1.3%)	0.4% (0.0%, 0.8%)
Seroma	(125)	0.6% (0.0%, 1.3%)	0.4% (0.0%, 0.8%)
Nipple Hypersensitivity	(97)	0.4% (0.0%, 1.0%)	0.4% (0.0%, 0.8%)
Nipple Paresthesia	(101)	0.4% (0.0%, 1.0%)	0.3% (0.0%, 0.7%)
Fluid Accumulation	(45)	0.4% (0.0%, 1.0%)	0.2% (0.0%, 0.5%)
Skin Paresthesia	(133)	0.4% (0.0%, 1.0%)	0.3% (0.0%, 0.7%)
Capsule Calcification	(33)	0.2% (0.0%, 0.7%)	0.1% (0.0%, 0.3%)
Lymphadenopathy	(89)	0.2% (0.0%, 0.7%)	0.1% (0.0%, 0.3%)
Implant Extrusion	(57)	0.2% (0.0%, 0.6%)	0.1% (0.0%, 0.3%)
Lymphedema	(93)	0.2% (0.0%, 0.6%)	0.1% (0.0%, 0.3%)
Tissue or Skin Necrosis	(145)	0.2% (0.0%, 0.6%)	0.1% (0.0%, 0.3%)
Wrinkling/Rippling	(149)	0.2% (0.0%, 0.6%)	0.2% (0.0%, 0.5%)
Implant Visibility	(69)	0.0% —	0.0% —
Infection	(73)	0.0% —	0.0% —
Irritation	(77)	0.0% —	0.0% —
Pneumothorax	(113)	0.0% —	0.0% —
Skin Hypersensitivity	(129)	0.0% —	0.0% —

Among the complications observed for augmentation patients, the highest 2-year cumulative risk rates by patient were for swelling (6.8%), capsular contracture (6.7%), and breast pain (5.0%). All other complications occurred at a by-patient risk rate of less than 5.0%.

The highest incidence rate across all complications was for swelling at 4 weeks post-implant (5.9%). The highest prevalence rate across all complications was for swelling at 4 weeks post-implant (5.9%). All of the swelling complications occurred within 1 year of implantation.

Median time to resolution among patients whose complications were resolved ranged from 3 days (implant extrusion) to 375 days (implant palpability). Among patients without resolution, median elapsed treatment time ranged from 42 days (capsule calcification) to 931 days (wrinkling/rippling). Inamed has contacted sites for patients who had unresolved complications with an elapsed time greater than one year in order to inquire about the status of follow-up on the complication.

The following table summarizes the resolution status for each complication during the 2-year period of this report. Overall, more than three fourths (80.0%) of complications were resolved.

Complication	(Table #)	Resolution Status		
		Unresolved	Resolved	% Resolved
Asymmetry	(24)	5	5	50.0%
Breast Pain	(28)	5	19	79.2%
Bruising	(32)	0	6	100.0%
Capsule Calcification	(36)	1	0	0.0%
Capsular Contracture	(40)	8	24	75.0%
Delayed Wound Healing	(44)	1	2	66.7%
Fluid Accumulation	(48)	0	2	100.0%
Hematoma	(52)	0	4	100.0%
Hypertrophic Scarring	(56)	2	6	75.0%
Implant Extrusion	(60)	0	1	100.0%
Implant Malposition	(64)	2	10	83.3%
Implant Palpability	(68)	2	1	33.3%
Implant Visibility	(72)	0	0	N/A
Infection	(76)	0	0	N/A
Irritation	(80)	0	0	N/A
Loss of Nipple Sensation	(84)	3	12	80.0%
Loss of Skin Sensation	(88)	1	5	83.3%
Lymphadenopathy	(92)	1	0	0.0%
Lymphedema	(96)	0	1	100.0%
Nipple Hypersensitivity	(100)	0	2	100.0%
Nipple Paresthesia	(104)	1	1	50.0%
Other Abnormal Scarring	(108)	1	3	75.0%
Other Nipple Related Observation	(112)	1	6	85.7%
Pneumothorax	(116)	0	0	N/A
Ptosis	(120)	2	4	66.7%
Redness	(124)	0	4	100.0%
Seroma	(128)	0	3	100.0%
Skin Hypersensitivity	(132)	0	0	N/A
Skin Paresthesia	(136)	0	2	100.0%
Skin Rash	(140)	0	8	100.0%
Swelling	(144)	3	30	90.9%
Tissue or Skin Necrosis	(148)	0	1	100.0%
Wrinkling/Rippling	(152)	1	0	0.0%
Other Complications	(156)	1	2	66.7%
Total (N=205)		**41**	**164**	**80.0%**

The following table summarizes the method of resolution for each complication that was resolved. Nearly half (47.0%) of resolved complications were resolved without any type of treatment. More than one fourth (29.3%) of resolved complications were resolved with non-surgical treatment.

Complication (Table #)	Method of Resolution			
	Reoperation and Explantation	Reoperation without Explantation	Non-Surgical Treatment	Without Treatment
Asymmetry (24)	2	1	2	0
Breast Pain (28)	0	0	6	13
Bruising (32)	0	0	2	4
Capsule Calcification (36)	0	0	0	0
Capsular Contracture (40)	4	12	6	2
Delayed Wound Healing (44)	0	1	0	1
Fluid Accumulation (48)	0	0	1	1
Hematoma (52)	0	4	0	0
Hypertrophic Scarring (56)	0	3	3	0
Implant Extrusion (60)	1	0	0	0
Implant Malposition (64)	0	6	2	2
Implant Palpability (68)	0	0	0	1
Implant Visibility (72)	N/A	N/A	N/A	N/A
Infection (76)	N/A	N/A	N/A	N/A
Irritation (80)	N/A	N/A	N/A	N/A
Loss of Nipple Sensation (84)	0	0	0	12
Loss of Skin Sensation (88)	0	0	1	4
Lymphadenopathy (92)	0	0	0	0
Lymphedema (96)	0	0	0	1
Nipple Hypersensitivity (100)	0	0	0	2
Nipple Paresthesia (104)	0	0	0	1
Other Abnormal Scarring (108)	0	2	0	1
Other Nipple Related Observation (112)	0	0	3	3
Pneumothorax (116)	N/A	N/A	N/A	N/A
Ptosis (120)	0	2	2	0
Redness (124)	0	0	3	1
Seroma (128)	0	0	2	1
Skin Hypersensitivity (132)	N/A	N/A	N/A	N/A
Skin Paresthesia (136)	0	0	0	2
Skin Rash (140)	0	0	8	0
Swelling (144)	0	0	5	25
Tissue or Skin Necrosis (148)	0	1	0	0
Wrinkling/Rippling (152)	0	0	0	0
Other Complications (156)	0	0	2	0
Total (N=164)	7	32	48	77

For historical comparison purposes, Appendix G summarizes the 2-year risk rates for augmentation patients from this Core Clinical Study and for augmentation patients from the 1995 Saline Augmentation Clinical Study (A95).

Table 157 summarizes the worst case severity level reported for each complication by patient. On a 1 (very mild) to 5 (very severe) severity scale, the highest average severity levels are associated with capsule calcification ($M = 5.0$, n = 1), lymphedema ($M = 5.0$, n = 1), skin paresthesia ($M = 4.0$, n = 2), and tissue or skin necrosis ($M = 4.0$, n = 1). The lowest average severity levels are associated with implant extrusion ($M = 1.0$, n = 1), skin hypersensitivity ($M = 1.3$, n = 3), irritation ($M = 1.5$, n = 2), implant palpability ($M = 1.7$, n = 11), and bruising ($M = 1.9$, n = 42).

3. Implant Rupture

Tables 158 – 162

Tables 158-162 present the results pertaining to implant rupture. A total of 9 of the 987 primary implants (0.9%) showed evidence of rupture: 1 device was identified as ruptured at explant, 5 devices were suspected of rupture via MRI, 2 devices were identified as suspected rupture during reoperation, and 1 device was suspected of rupture via physician exam (specifically, the patient had been in a motor vehicle accident and was experiencing breast pain/tenderness), (Table 158). Of the 9 suspected implant ruptures, 2 were confirmed to be ruptured on explant, 5 were false reports of rupture whereby the devices were found to be intact (1 false report was identified upon explant, 3 false reports were identified by follow-up mammogram, and 1 false report was identified by follow-up ultrasound), and 2 devices have unconfirmed rupture status (Table 159).

Based on confirmed and unconfirmed ruptures, the 2-year risk of implant rupture was 0.9% by patient and 0.4% by implant (Table 160). The 2-year incidence of implant rupture was 0.4%, and the 2-year prevalence of implant rupture was 0.6% by patient (Table 161). Of the 4 implant ruptures by patient through 2 years post-implant, 2 are as yet unresolved (Table 162).

4. Reoperations

Tables 163 – 170

Tables 163-170 present results pertaining to reoperations performed through 2 years.

The 2-year risk of reoperation for any reason was 17.1% by patient and 13.2% by implant (Table 163).

A total of 91 reoperations were performed on 81 patients (16.4% of 494 enrolled augmentation patients) through 2 years post-implant (Table 164). Most of the 81 patients (87.7%) had one reoperation; 10 patients (12.3%) had two reoperations.

No intraoperative complications were reported for any of the 91 reoperations (Table 165).

Among the 91 reoperations, the primary reasons for reoperation were capsular contracture (34.1%), malposition (16.5%), and ptosis (13.2%), (Table 166). The primary procedure performed during reoperation was most commonly implant removal with replacement (23.1%), capsulotomy (15.4%), or mastopexy (13.2%), (Table 167). In sum, the most frequently performed reoperations were capsule procedure for capsular contracture (20.9%), implant replacement/removal due to capsular contracture (13.2%), and mastopexy due to unsatisfactory cosmetic result (13.2%), (Table 168).

During the 91 reoperations, a total of 195 individual surgical procedures were performed (Table 169). The majority of reoperations (75.8%) involved only one or two surgical procedures (e.g., bilateral implant replacement/removal is counted as two procedures). Of the 195 procedures performed, the most common procedures were implant removal with replacement (20.0%), capsulotomy (20.0%), and mastopexy (16.4%), (Table 170).

5. Implant Replacement/Removal

Tables 171 – 177

Tables 171-177 describe the occurrence of implant replacement/removal. The 2-year risk of implant replacement/removal (i.e., device explant with or without replacement) was 4.7% by patient and 4.4% by implant (Table 171). The 2-year risk of implant removal with replacement was 4.5% by patient and 4.2% by implant (Table 172), and the 2-year risk of implant removal without replacement was 0.2% by patient and 0.2% by implant (Table 173).

Of the 41 primary explanted devices, the most common reasons for replacement/removal were capsular contracture (46.3%), patient request for a style/size change (17.1%), and malposition (14.6%), (Table 174).

Of the 41 explanted devices, 2 were confirmed ruptured upon explantation (Table 175). Both devices had intact capsules and gel on the implant surface. Neither device had evidence of extracapsular gel, and physicians indicated that removal was not difficult for either device. Of the 39 remaining non-ruptured devices, none had a torn capsule, gel on the implant surface, or extracapsular gel. Physicians indicated that removal was difficult for 2 of the 39 non-ruptured implants.

A total of 39 of the 41 explanted devices were replaced (95.1%), (Table 176). Of the devices replaced, most (84.6%) were replaced with another McGhan study device. Of the 33 implants replaced with McGhan study devices, 75.8% were replaced with a larger size, 18.2% were replaced with the same size implant as the primary study device, and 6.1% were replaced with a smaller size (Table 177).

A summary of the medical complications listed in Methods Section D.3.b that occurred following removal and replacement of a primary study device are listed in Appendix H. Patients' assessment of their implants following replacement of all primary study devices also is presented in Appendix H.

6. Risk of Any Complication

Tables 178 – 180

Tables 178-180 present the risk of specific groupings of complications through 2 years post-implant. The 2-year by-patient risk of any general breast surgery complication is 19.8% (Table 178). The 2-year by-patient risk of any breast implant surgery – cosmetic complication is 6.0% (Table 179). The 2-year by-patient risk of any breast implant surgery – non-cosmetic complication is 7.7% (Table 180). It is important to note that these risks are not additive because a patient may experience more than one type of complication and would be included in the risk for each type of complication.

D. PRE- VS. POST- IMPLANT MEDICAL HISTORY

1. Reproduction and Lactation Problems

Tables 181 – 184

Tables 181 and 182 report pre- and post-implant reproduction problems. Eighty-one (81) of the 494 augmentation patients (16.4%) experienced pre-implant reproduction problems, most frequently spontaneous abortion/miscarriage (Table 181). Through 2 years post-implant, 5 patients (1.0%) had a total of 5 reproduction problems: 4 spontaneous abortions/miscarriages and 1 other reproduction problem (endometriosis), (Table 182). One of the 5 patients who had a post-implant reproduction problem also had a pre-implant reproduction problem. This patient had a planned abortion to treat a medical problem prior to implant surgery and spontaneous abortion (miscarriage) post-implant.

Tables 183 and 184 report pre- and post-implant lactation problems. Forty-two (42) of the 494 augmentation patients (8.5%) experienced pre-implant lactation problems, most frequently inadequate milk production and mastitis requiring treatment (Table 183). Through 2 years post-implant, 4 patients (0.8%) reported a total of 8 lactation problems: 1 mastitis not requiring treatment, 2 mastitis requiring treatment, 2 inadequate milk production, 1 excess milk production, 1 pain, and 1 other problem (decrease volume milk, still adequate), (Table 184).

2. Breast Cancer and Benign Breast Disease

Table 185 – 188

Tables 185 and 186 report pre- and post-implant occurrences of breast disease. Thirty (30) of the 494 augmentation patients (6.1%) reported pre-implant breast disease, of which 29 were benign disease and 1 was unknown breast disease (Table 185). Through 2 years post-implant, 27 patients (5.5%) had an occurrence of breast disease: 1 with confirmed malignant disease, 25 with benign disease, and 1 with unknown breast disease (Table 186). Four (4) of the 25 patients who had post-implant benign breast disease also had pre-implant benign breast disease.

Tables 187 and 188 report the results of pre- and post-implant mammograms. Five (5) of the 494 augmentation patients (1.0%) had a pre-implant abnormal mammogram result (Table 187). Of these 5 patients with abnormal results, 4 had benign breast disease and 1 had unknown breast disease. Through 2 years post-implant, 136 patients had a mammogram, of which 8 showed an abnormal result (Table 188). Of the 8 patients with abnormal mammogram results, 1 had no breast disease and 7 had benign breast disease.

3. Connective Tissue/Autoimmune Disease

Table 189 – 190

Tables 189 and 190 report pre- and post-implant occurrences of connective tissue/autoimmune disease (CTD). None of the augmentation patients reported a CTD pre-implant (Table 189).

Through 2 years post-implant, one (1) patient reported a connective tissue/autoimmune disease (Table 190). Specifically, this 46-year-old patient had a confirmed report of rheumatoid arthritis with an onset date of 18 months after her primary implant surgery.

E. EFFECTIVENESS ASSESSMENT

1. Changes in Anatomical Configuration

Tables 191 – 194

Tables 191-194 report changes in patients' anatomical configuration pre- vs. post-implant.

Of the 408 patients with both a valid pre- and post-implant bra size, the majority of patients increased the size of their breasts by either one cup size (40.4%) or two cup sizes (45.3%), (Tables 191 and 192). The remaining patients increased by more than two cup sizes (8.3%), maintained the same cup size (5.4%), or showed a decrease in cup size (0.5%). For these latter patients, a cup size increase was not observed for a variety of reasons, including the purpose of implant surgery (e.g., to improve the shape and fullness of the breast, to correct congenital asymmetry) and an atypical pre-implant breast measurement (e.g., larger than normal cup size due to menstruation).

When bra sizes were converted to a numerical scale score from 1 to 13, the results revealed a statistically significant increase in bra size from pre-implant ($M = 4.7$) to post-implant ($M = 6.6$), ($p < .001$), (Table 193).

In terms of lateral breast measurement, a statistically significant increase was observed from pre-implant ($M = 17.4$) to post-implant ($M = 22.1$), ($p < .001$), (Table 194).

2. Satisfaction with Outcome

Tables 195 – 201

Tables 195-197 report physician satisfaction with the implant surgery based on primary study devices. More than 95% of physicians indicated being satisfied with the results of breast implant surgery at each of the four follow-up visit intervals (Table 195). Indeed, on a 1 (definitely dissatisfied) to 5 (definitely satisfied) scale, the average satisfaction level for physicians was either 4.8 or 4.9 at each follow-up interval. Very few physicians specified any type of dissatisfaction about the implant surgery at any of the follow-up intervals (Table 196). Of those physicians who did specify a dissatisfaction about the outcome of the patient's surgery, most were medical/procedural in nature (e.g., 82.8% at 2 years post-implant), (Table 197).

Tables 198-200 report patient satisfaction with the implant surgery based on primary study devices. More than 95% of patients indicated being satisfied with the results of breast implant surgery at each of the four follow-up visit intervals (Table 198). On a 1 (definitely dissatisfied) to 5 (definitely satisfied) scale, the average satisfaction level for patients was either 4.8 or 4.9 at each follow-up interval. Very few patients specified any type of dissatisfaction about their implant surgery at any of the follow-up intervals (Table 199). Of those patients who did specify a dissatisfaction about the outcome of their breast implant surgery, 100% were aesthetic at 0-4 weeks post-implant. By 2 years post-implant, most patient dissatisfactions specified (76.5%) were medical/procedural in nature (Table 200).

Table 201 reports patient satisfaction with the implant surgery based on both primary and secondary study devices. Again, more than 95% of patients indicated they were satisfied with the results of their breast implant surgery at each follow-up visit interval, with the average patient satisfaction level between 4.7 and 4.9 at each follow-up visit interval.

3. Quality of Life

The quality of life results reported are based on all augmentation patients with McGhan Silicone-Filled Breast Implants, including both primary and secondary study devices.

a. Motivation for Surgery

Table 202

Table 202 reports on patients' motivation for surgery. The majority of the augmentation patients (87.4%) rated "to make me feel better about my physical appearance" as "quite a bit" or "extremely" important to them as a reason for having breast implant surgery. In contrast, most patients (87.2%) rated "to increase my chance of meeting a partner" as "not at all" important to them as a reason for their implant surgery.

b. Expectation and Satisfaction with Implants

Tables 203 – 209

Tables 203-204 present patients' pre-operative expectation vs. post-implant satisfaction with their breast implants. Patients were highly satisfied with their breast

implants, with a mean satisfaction score of 4.6 on a 5-point scale at both 1 and 2 years post-implant (Table 203). Statistically, patients' post-operative satisfaction was lower ($M = 4.6$) than their pre-operative expectation ($M = 4.9$), ($p < .001$). However, well above 90% of augmentation patients indicated being "satisfied" or "very satisfied" with their breast implants post-operatively (97.5% at 1 year post-implant and 94.8% at 2 years post-implant), (Table 204).

Tables 205-209 present summary results from the scales that measured expectation and perceived results of implant surgery (i.e., Rowland). The results obtained from the Rowland expectation instrument are summarized in Table 205 and the details are provided in separate tables for the subscales of improve self image (Table 206), improve social relations (Table 207), and improve daily living (Table 208). The results for all three subscales showed significant improvement after implant surgery. Table 209 (Rowland Expectation: Improve Well-Being) was included and intentionally left blank to correspond with the table numbers in the Core Clinical Study - Reconstruction Cohort Report.

c. Comparison of Baseline SF-36 Scores to the General U.S. Female Population

Table 210

At baseline, augmentation patients scored significantly higher ($p < .001$) than did the general U.S. female population on all 8 of the SF-36 scales for which comparative values are available (Table 210). The largest difference (29.4%) was seen in the scale that measures vitality.

d. General Health

Tables 211 – 226

Tables 211 through 226 present summary results from the concepts that measured general health/well being (i.e., MOS-20 and SF-36 surveys). The results obtained from the SF-36 survey are summarized in Table 211 and the details are provided in separate tables for the subscales of role limitations due to emotional problems (Table 212), role limitations due to physical health problems (Table 213), general health (Table 214), bodily pain (Table 215), social functioning (Table 216), physical functioning (Table 217), vitality (Table 218), mental health (Table 219), and reported health transition (Table 220). The results obtained from the MOS-20 survey are summarized in Table 221 and the details are provided in separate tables for the subscales of health perceptions (Table 222), physical functioning (Table 223), role functioning (Table 224), social functioning (Table 225), and mental health (Table 226).

The results for some of the subscales showed scores that slightly, but statistically significantly, decreased after implantation: role limitations due to emotional problems (SF-36), role limitations due to physical health problems (SF-36), general health (SF-36), social functioning (SF-36), vitality (SF-36), mental health (SF-36), health perceptions (MOS-20), and mental health (MOS-20). However, the magnitude of the

differences was small and the post-implant quality of life scores (SF-36) remained well above those of the general U.S. female population. Other general health scales did not show statistically significant differences: bodily pain (SF-36), physical functioning (SF-36), physical functioning (MOS-20), role functioning (MOS-20), and social functioning (MOS-20). One scale, reported health transition (SF-36), showed a statistically significant increase after implantation.

e. Depression Screen

Table 227

Of the three measures of depression, one revealed a statistically significant finding: the number of patients who indicated feeling depressed during "two or more weeks in the past year" increased significantly between 1 and 2 years post-implant ($p = .014$), (Table 227). However there was no significant difference in the number of patients indicating they felt depressed between baseline/pre-implant and either 1 year or 2 years post-implant.

f. Self-Concept and Self-Esteem

Table 228 – 229

Results on the Tennessee Self-Concept Physical Self Scale revealed a statistically significant increase pre-implant vs. 1 year post-implant in the way patients view their bodies and state of health, and their attitude about appearance, skills, and sexuality ($p = .04$), (Table 228).

Results on the Rosenberg Self-Esteem Scale revealed no significant difference pre- vs. post-implant in patients' self-esteem (Table 229).

g. Body Image

Table 230 – 235

Results on the Self vs. Breast Semantic Differential Scale revealed no significant difference in how patients rated themselves relative to their breasts pre- vs. post-implant (Table 230).

Table 231 presents summary results for the Body Esteem Scale and each subscale. Findings for the full scale indicated a significant improvement in patients' overall body esteem ($p = .03$), (Table 232). The sexual attractiveness subscale showed a significant positive increase pre- vs. post-implant ($p < .001$), (Table 233). The weight concern subscale showed no change pre- vs. post- implant (Table 234). The physical condition subscale showed a significant decrease pre- vs. post-implant ($p < .001$), (Table 235). The largest effect size (0.42) was observed for the increase in score pre- vs. post-implant for the sexual attractiveness subscale.

h. Satisfaction

Tables 236 – 248

Table 236 presents summary results for the quality of life measurement of patient satisfaction. Only the personal life satisfaction scale did not show a significant change pre- vs. post-implant (Tables 237 and 238). All other satisfaction scales showed a significant positive increase pre- vs. post-implant ($p < .001$). Patient satisfaction with her breasts increased significantly from pre-implant (M =1.9) to post-implant (M = 4.5), on a 1 (very dissatisfied) to 5 (very satisfied) scale (Tables 239 and 240). Patient ratings of how well her breasts matched increased significantly from pre-implant (M = 3.9) to post-implant (M = 5.2), on a 1 (very poor) to 6 (excellent) scale (Tables 241 and 242). Patient satisfaction with her breast shape increased significantly from pre-implant (M = 2.4) to post-implant (M = 4.4), on a 1 (very dissatisfied) to 5 (very satisfied) scale (Tables 243 and 244). Patient satisfaction with her breast size increased significantly from pre-implant (M = 1.9) to post-implant (M = 4.5), on a 1 (very dissatisfied) to 5 (very satisfied) scale (Tables 245 and 246). Finally, patient satisfaction with breast feel or touch increased significantly from pre-implant (M = 3.1) to post-implant (M = 4.3/4.4), on a 1 (very dissatisfied) to 5 (very satisfied) scale (Tables 247 and 248).

i. Worry

Tables 249 – 250

On average, patients expressed little worry about their breast implants and did not feel that any worry they experienced interfered with their daily activities (Tables 249 and 250).

j. Bodily Pain and Work/Activity Problems

Tables 251 – 252

On average, patients indicated experiencing very little bodily pain and no problems with work/activities due to their breast implants (Tables 251 and 252).

F. RISK FACTOR ANALYSIS

1. Reoperation

Tables 253 – 254

Of the 987 primary study implants, 125 have been involved in a reoperation (Table 163). Results from the Cox proportional hazards regression analysis revealed that 1 of the 7 characteristics examined was significantly related to reoperation (Wald χ^2= 16.6, $p <$ .001).

a. Incision Site

A total of 46.2% of implants placed with "other" incision sites were involved in a reoperation vs. implants placed with axillary (14.5%), inframammary (12.3%), or periareolar (11.3%) incision sites (Table 253). Implants inserted via "other" incision sites had over 4 times greater risk of reoperation vs. periareolar (5.7 times greater risk), inframammary (5.3 times greater risk), or axillary (4.4 times greater risk) incision sites (Table 254).

2. Implant Replacement/Removal

Tables 255 – 256

Of the 987 primary study implants, 41 have been explanted (Table 171). Results from the Cox proportional hazards regression analysis revealed that 3 of the 7 characteristics examined were significantly related to implant replacement/removal (Wald $\chi^2 = 24.1$ $p < .001$).

a. Pocket Irrigation – Antibiotics

A total of 3.4% of implants placed with antibiotics in the pocket underwent implant replacement/removal vs. 6.6% of implants placed without antibiotics in the pocket (Table 255). Use of antibiotics in the pocket was found to be a protective factor against implant replacement/removal (Table 256). Implants placed without antibiotics in the pocket had a 2.6 times greater risk of implant replacement/removal than did implants placed with the use of antibiotics in the pocket.

b. Pocket Irrigation – Betadine

A total of 2.5% of implants placed with betadine in the pocket underwent implant replacement/removal vs. 5.2% of implants placed without betadine in the pocket (Table 255). Use of betadine in the pocket was found to be a protective factor against implant replacement/removal (Table 256). Implants placed without betadine in the pocket had a 2.8 times greater risk of implant replacement/removal than did implants placed with the use of betadine in the pocket.

c. Device Texture

A total of 6.3% of smooth implants underwent implant replacement/removal vs. 1.6% of textured devices (Table 255). Smooth devices had a 4.3 times greater risk of implant replacement/removal than did textured devices (Table 256).

3. Implant Rupture

Tables 257 – 258

Of the 987 primary study implants, 4 had implant rupture (Table 160). Results from the Cox proportional hazards regression analysis revealed that none of the 7 characteristics examined were significantly related to implant rupture.

4. Capsular Contracture

Tables 259 – 260

Of the 987 primary study implants, 48 had capsular contracture (Table 37). Results from the Cox proportional hazards regression analysis revealed that none of the 7 characteristics examined was significantly related to capsular contracture.

5. Infection

Tables 261 – 262

Of the 987 primary study implants, none have experienced an infection (Table 73). Therefore, a Cox proportional hazards regression analysis was not performed to assess if any of the characteristics were related to infection.

DISCUSSION

Overall, the results of this study revealed that McGhan Silicone-Filled Breast Implants are both safe and effective devices for use in augmentation of the normal breast. This conclusion is based on data from a total of 494 augmentation patients who received these devices and were followed for 2 years post-implant. Patient follow-up compliance was quite high in this study, with an adjusted compliance rate of 85.7% at 1 year and 89.8% at 2 years post-implant. Thus, the results obtained in this study are based on a sufficient number of enrolled patients.

In terms of the safety of McGhan Silicone-Filled Breast Implants, results revealed clinically acceptable rates for medical complications and reoperations at 2 years post-implant. The highest 2-year by-patient risk rates for medical complications were swelling (6.8%), capsular contracture (6.7%), and breast pain (5.0%). The lowest 2-year by-patient risk rates, all of which were 0%, were for implant visibility, infection, irritation, pneumothorax, and skin hypersensitivity. In general, there were very few occurrences of most of the 34 potential medical complications assessed in this study through 2 years post-implant.

Most patients experienced a resolution to their complications within the 2-year period of data collection in this study. The remaining patients are either currently undergoing treatment, had previously refused treatment, or had a complication where treatment was not possible (e.g., loss of nipple sensation). Of the majority of complications that were resolved, nearly half were resolved without any type of treatment and more than one fourth were resolved with non-surgical treatment. Less than one fourth of complications required reoperation to resolve, and most that did involve reoperation did not involve device explant.

A total of 9 devices were reported as suspected of rupture through 2 years post-implant. Three (3) of the 9 devices have been explanted and the other 6 devices remain implanted. Of the 9 suspected ruptures, 5 ruptures were false reports (i.e., the devices were found to be intact upon further follow-up), 2 devices were confirmed to be ruptured, and 2 devices are unconfirmed ruptures. Based on confirmed and unconfirmed ruptures, the 2-year by-patient risk of implant rupture was 0.9%.

The 2-year risk of reoperation was 17.1% by patient. Of all reoperations performed through 2 years post-implant, the most common were capsule procedure for capsular contracture (20.9%), implant replacement/removal due to capsular contracture (13.2%), and mastopexy due to unsatisfactory cosmetic result (13.2%). The 2-year risk of implant replacement/removal was 4.7% by patient. The most common reason for implant replacement/removal was capsular contracture (46.3%).

Overall, the 2-year complication risk rates observed for McGhan Silicone-Filled Breast Implants were either lower or equivalent to the 2-year complication risk rates observed for McGhan Saline-Filled Breast Implants in the 1995 Saline Augmentation Study (A95).

For those complications for which comparable 2-year risk rates are available, the risk for McGhan Silicone-Filled Breast Implants was significantly lower (as determined by non-overlapping 95% confidence intervals) for 13 of 27 safety outcomes assessed in both studies, including implant rupture/deflation. Eleven (11) complications showed nominally lower 2-year risk rates for McGhan Silicone-Filled Breast Implants (but with overlapping 95% confidence intervals), including reoperation and implant replacement/removal. One (1) complication (lymphadenopathy) showed the same 2-year risk rate, and 2 complications (skin rash and implant extrusion) showed nominally higher 2-year risk rates (but with overlapping 95% confidence intervals) for McGhan Silicone-Filled Breast Implants.

Through 2 years post-implant, 5 patients (1.0%) reported a total of 5 reproduction problems and 4 (0.8%) patients reported a total of 8 lactation problems. Through 2 years post-implant, 27 (5.5%) patients reported breast disease, of which 1 patient had confirmed malignant breast disease, 25 patients had reports of benign breast disease, and 1 patient had a report of a breast lump for which the outcome (benign or malignant) was unknown. One (1) 46-year-old patient (0.2%) reported a connective tissue disease through 2 years post-implant, specifically a confirmed diagnosis of rheumatoid arthritis 18 months after primary implant surgery.

In terms of effectiveness, McGhan Silicone-Filled Breast Implants were found to be highly effective in increasing the size of a woman's breast, with fully 94.1% of patients analyzed showing an increase of one or more bra cup sizes post-implant. The remaining patients either maintained the same bra cup size (5.4%) or showed a decrease in bra cup size (0.5%). For these latter patients, a bra cup size increase was not observed for a variety of reasons, including the purpose of implant surgery (e.g., to improve the shape and fullness of the breast, to correct congenital asymmetry) and an atypical pre-implant breast measurement (e.g., larger than normal cup size due to menstruation).

A variety of quality of life measures were assessed in this study, including general health-related concepts, self-concept, self-esteem, and body esteem. For the majority of general health concepts, average scores at 1 and 2 years post-implant were statistically significantly lower vs. baseline. However, the magnitude of the differences was small and the quality of life scores remained well above those of the general U.S. female population. The small decreases that were observed in a number of the quality of life scales utilized in this study may be related to the very high scores that were observed among patients at baseline. Compared with the general U.S. female population, the patients who enrolled in this study had significantly higher quality of life scores both pre- and post-implant. Upon re-testing a group with very high scores initially, observing a decrease in scores is a common statistical phenomenon referred to as "regression to the mean" (Campbell & Stanley, 1963). A small change between pre- and post-implant scores cannot unambiguously be attributed to breast implant surgery without comparison to a control group of women with similar pre-implant characteristics who did not obtain breast implant surgery. Such a control group was not included in this study.

In terms of patients' expectation and perceived results of breast implant surgery, significant positive change was observed pre- vs. post-implant in subscales that measured self image, social relations, and daily living. There was no significant change in patient's self-esteem. However, results did reveal a statistically significant increase pre- vs. post-implant in patients' physical self-concept. There was also a significant improvement in patients' overall body esteem post-implant, with the largest increase in the sexual attractiveness subscale.

In contrast to the general quality of life measures, patients' satisfaction with their breasts on a variety of assessments (i.e., how well breasts matched, breast shape, breast size, and breast feel) showed significantly increased scores at 1 and 2 years post-implant vs. baseline.

Patients were highly satisfied with their breast implants. More than 95% of both physicians and patients reported being satisfied with the outcome of the primary breast implant surgery at each of the follow-up visit intervals. Indeed, on a 1 (definitely dissatisfied) to 5 (definitely satisfied) scale, the average rating was between 4.8 and 4.9 at each follow-up interval. Patient ratings of satisfaction with their breasts from the quality of life questionnaire also revealed a highly significant increase, from a mean satisfaction score of 1.9 (out of 5) pre-implant to a mean score of 4.5 at 1 and 2 years post-implant.

In sum, the results of this study revealed that the risk of complications associated with breast implant surgery for augmentation, including reoperations, is relatively low and that women who undergo augmentation surgery are highly satisfied with the outcome. These results are consistent with previous findings that, despite the risks associated with breast implant surgery, women perceive significant positive benefit to the procedure (Handel et al., 1993; Young et al., 1994; McGhan Medical RTV Saline-Filled Mammary Implant PMA #P990074, Original PMA Volume 6).

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CORE AUGMENTATION TABLES

Table 1: Patient Age, Race, and Marital Status

Characteristic	Patients n	Patients %(N = 494)
Age		
18-19	5	1.0%
20-29	110	22.3%
30-39	232	47.0%
40-49	116	23.5%
50-59	30	6.1%
60-69	1	0.2%
70 & over	0	0.0%
	494	100.0%
Median = 34 years		
Range = 18 to 60 years		
Race		
Caucasian	415	84.0%
African-American	4	0.8%
Asian	18	3.6%
Hispanic	34	6.9%
Other	17	3.4%
Not Provided	10	2.0%
	498	100.8%
Marital Status		
Single	128	25.9%
Married	240	48.6%
Widowed	10	2.0%
Separated	15	3.0%
Divorced	101	20.4%
	494	100.0%

Table 2: Patient Occupation and Education

Characteristic	Patients n	Patients %(N = 494)
Occupation		
Clerical	49	9.9%
Professional	248	50.2%
Trade	9	1.8%
Service	43	8.7%
Student	33	6.7%
Housewife	85	17.2%
Other	28	5.7%
	495	100.2%
Education		
Less Than High School	6	1.2%
High School Graduate	70	14.2%
Some College	177	35.8%
College Graduate	192	38.9%
Post College	47	9.5%
Not Provided	2	0.4%
	494	100.0%

Table 3: Pre-Implant Height and Weight

Characteristic	Patients n	Patients %(N = 494)
Height		
4'11" & under	5	1.0%
5'0" - 5'2.9"	69	14.0%
5'3" - 5'5.9"	185	37.4%
5'6" - 5'8.9"	198	40.1%
5'9" - 5'11.9"	35	7.1%
6'0" & over	2	0.4%
	494	100.0%
Median = 5'5"		
Range = 4'10" to 6'0"		
Weight		
99 lbs & under	12	2.4%
100 - 109	51	10.3%
110 - 119	107	21.7%
120 - 129	129	26.1%
130 - 139	112	22.7%
140 - 149	48	9.7%
150 - 159	16	3.2%
160 lbs & over	18	3.6%
Not Provided	1	0.2%
	494	100.0%
Median = 125 lbs		
Range = 90 to 200 lbs		

Table 4: Product Styles

Product Style	Implants	
	n	%(N = 987)
Smooth		
Style 40 (round)	420	42.6%
Style 45 (round)	120	12.2%
	540	54.7%
Textured		
Style 110 (round)	244	24.7%
Style 120 (round)	128	13.0%
Style 153 (shaped)	75	7.6%
	447	45.3%

Table 5: Product Style 40

Size	Implants	
	n	%(N = 420)
80cc	1	0.2%
100cc	0	0.0%
120cc	0	0.0%
140cc	2	0.5%
160cc	1	0.2%
180cc	14	3.3%
200cc	10	2.4%
220cc	8	1.9%
240cc	26	6.2%
260cc	23	5.5%
280cc	50	11.9%
300cc	74	17.6%
320cc	60	14.3%
340cc	55	13.1%
360cc	48	11.4%
400cc	37	8.8%
460cc	5	1.2%
500cc	4	1.0%
560cc	2	0.5%
	420	100.0%

Table 6: Product Style 45

Size	Implants	
	n	%(N = 120)
120cc	0	0.0%
160cc	0	0.0%
200cc	0	0.0%
240cc	12	10.0%
280cc	32	26.7%
320cc	44	36.7%
360cc	22	18.3%
400cc	4	3.3%
460cc	6	5.0%
500cc	0	0.0%
550cc	0	0.0%
600cc	0	0.0%
650cc	0	0.0%
700cc	0	0.0%
800cc	0	0.0%
	120	100.0%

Table 7: Product Style 110

Size	Implants	
	n	%(N = 244)
90cc	0	0.0%
120cc	0	0.0%
150cc	4	1.6%
180cc	2	0.8%
210cc	6	2.5%
240cc	33	13.5%
270cc	28	11.5%
300cc	34	13.9%
330cc	37	15.2%
360cc	46	18.9%
390cc	29	11.9%
420cc	15	6.1%
450cc	8	3.3%
480cc	0	0.0%
510cc	2	0.8%
	244	100.0%

Table 8: Product Style 120

Size	Implants	
	n	%(N = 128)
180cc	0	0.0%
220cc	1	0.8%
260cc	12	9.4%
300cc	20	15.6%
340cc	45	35.2%
400cc	44	34.4%
440cc	0	0.0%
500cc	3	2.3%
550cc	0	0.0%
600cc	1	0.8%
650cc	2	1.6%
	128	100.0%

Table 9: Product Style 153

Size	Implants	
	n	%(N = 75)
360cc	40	53.3%
450cc	29	38.7%
540cc	4	5.3%
630cc	2	2.7%
720cc	0	0.0%
	75	100.0%

Table 10: Indication for Implant Placement

Indication	Patients	
	n	%(N = 494)
Asymmetry	61	12.3%
Ptosis	76	15.4%
Aplasia	22	4.5%
Dissatisfaction with Breast Size/Shape	335	67.8%
	494	100.0%

Table 11: Anesthesia and Surgical Facility

Characteristic	Patients	
	n	%(N = 494)
Anesthesia		
General	375	75.9%
Local	119	24.1%
	494	100.0%
Surgical Facility		
Doctor's Office	235	47.6%
Hospital	63	12.8%
Free Standing Surgical Facility	196	39.7%
	494	100.0%

Table 12: Incision Site

Incision Site	Implants	
	n	%(N = 987)
Periareolar	388	39.3%
Inframammary	462	46.8%
Mastectomy Scar	0	0.0%
Axillary	124	12.6%
Breast Scar	4	0.4%
Mastopexy Incision With Implant Placement	9	0.9%
Other	0	0.0%
	987	100.0%

Table 13: Implant Location

Implant Location	Implants	
	n	%(N = 987)
Subcutaneous	6	0.6%
Subglandular	307	31.1%
Submuscular-Partial	580	58.8%
Submuscular-Complete	94	9.5%
	987	100.0%

Table 14: Drains Placed

Drains Placed	Implants	
	n	%(N = 987)
Yes	184	18.6%
No	803	81.4%
	987	100.0%

Table 15: Concurrent Breast Procedures

	Implants	
Concurrent Breast Procedures	n	%(N = 987)
No Concurrent Procedure	841	85.2%
Concurrent Procedure	146	14.8%
	987	100.0%

Type Of Concurrent Procedure	n	%(N = 146)
Biopsy	1	0.7%
Mastectomy	5	3.4%
Mastopexy	128	87.7%
Nipple Areolar Complex	12	8.2%
Reduction	6	4.1%
Removal of Excess Tissue/Lesion/Cyst	2	1.4%
	154*	105.5%

* The sum of concurrent procedures listed may exceed the total number of implants with concurrent procedures because an implant surgery may have involved more than one concurrent procedure.

CORE STUDY - AUGMENTATION

Table 16: Intraoperative Medication - Pocket Irrigation

	Implants	
Pocket Irrigation	n	%(N = 987)
No Pocket Irrigation	76	7.7%
Pocket Irrigation	911	92.3%
	987	100.0%

Type Of Pocket Irrigation	n	%(N = 911)
Steroid	8	0.9%
Antibiotic	761	83.5%
Betadine	396	43.5%
Local Anesthetic	318	34.9%
Unknown	2	0.2%
	1485*	163.0%

* The sum of pocket irrigations listed may exceed the total number of implants with pocket irrigation because an implant surgery may have involved more than one type of pocket irrigation.

Table 17: Intraoperative Medication - Parenteral Medication

	Patients	
Parenteral Medication	n	%(N = 494)
No Parenteral Medications	67	13.6%
Parenteral Medication	427	86.4%
	494	100.0%

Type Of Parenteral Medication	n	%(N = 427)
Antibiotics	424	99.3%
Steroid	152	35.6%
Anesthetic	2	0.5%
Sedative	48	11.2%
Other	21	4.9%
	647*	151.5%

Table 17 (Cont.): Intraoperative Medication - Parenteral Medication

Other Parenteral Medication Specified (N = 21)

Pt Seq#	Other Parenteral Medication Specified
001	VERSED,KETALAR,DILAUDID,CEFAZOLIN,INAPSINE SOLU MEDROL
002	VERSED,KETALAR,ZOFRAN,GEFAZOLIN,DILAUDID, SOLU MEDROL
003	REGEAN,VERSED,KETALAR
004	REGLAN,VERSED,KETALAR
005	REGLAN,KETALAR,VERSED
006	REGLAN,VERSED,KETALAR
007	VERSED,FENTANGE,KETALAR
008	VERSED,KETALAR,REGLAN
009	VERSED,KETALAR,REGEAN
010	KETALAR,VERSED,REGLAN
011	VERSED,KETALAR,REGLAN
012	VERSED,KETALAR,EPHEDRINE
013	VERSED,KETLAR,REGLAN
014	VERSED,FENTANYL,REGLAN
015	VERSED,KETALAR,REGLAN
016	VERSED,KETALAR,FENTARYL,REGLAN
017	VERSED,KETALAR,FENTANYL,REGLAN
018	VERSED,KETALAR,REGLAN
019	VERSED,FENTANYL,REGLAN
020	VERSED,KETALAR,REGLAN
021	REGLAN 10 MG

* The sum of parenteral medications listed may exceed the total number of patients with parenteral medication because a patient may have had more than one type of parenteral medication.

Table 18: Intraoperative Complications

Intraoperative Complications	Implants	
	n	%(N = 987)
Yes	0	0.0%
No	987	100.0%
	987	100.0%

Table 19: Patient Compliance Through 2 Years

	0-4 Weeks	6 Months	1 Year	2 Years
Theoretically Due	494	494	494	494
Deaths*	0	0	0	0
Explant-Related Discontinuations*	0	1	3	5
Without Replacement	0	0	0	1
Replacement with Non-Study Device	0	1	2	2
Unknown Replacement Status	0	0	1	2
Expected	494	493	491	489
Actual Evaluated	489	412	421	439
Lost-to-Follow-Up	5	81	70	50
% Follow-Up	99.0%	83.6%	85.7%	89.8%

* Deaths and Explant-Related Discontinuations are reported cumulatively.

Table 20: Patient Discontinuation Through 2 Years

Discontinuation	Patients (N = 494) n	%
Not Discontinued	484	98.0%
Discontinued		
Death	0	0.0%
Explanted of All Study Devices	8	1.6%
Patient Choice	2	0.4%
	494	100.0%

Patient Choice Discontinuation Specified (N = 2)

Pt Seq#	Patient Choice Discontinuation
001	DISTANCE TO TRAVEL.4 CHILDREN,1 SICK
002	PT REQUESTS SHE BE DISCONTINUED. PT REFUSES TO COME FOR FOLLOW-UP

CORE STUDY - AUGMENTATION

Table 21: Risk of First Occurrence of Asymmetry

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	4	477	0.8% (0.0%, 1.6%)		N/A	
6 Months	5	468	1.0% (0.1%, 1.9%)		N/A	
1 Year	6	456	1.2% (0.3%, 2.2%)		N/A	
2 Years	10	416	2.1% (0.8%, 3.4%)		N/A	

CORE STUDY - AUGMENTATION

Table 22: Incidence and Prevalence of Asymmetry

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	4 (0.8%)	4 (0.8%)	493		N/A	
6 Months	1 (0.2%)	5 (1.0%)	481		N/A	
1 Year	1 (0.2%)	5 (1.1%)	473		N/A	
2 Years	4 (0.9%)	7 (1.5%)	462		N/A	

CORE STUDY - AUGMENTATION

Table 23: Time to Resolution of Asymmetry

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 5)	
Minimum	1
Median	355
Maximum	728
Resolved - Time To Resolution (N = 5)*	
Minimum	59
Median	207
Maximum	700

* Includes 1 occurrence of Asymmetry that was resolved after explantation of the patient's primary study device.

CORE STUDY - AUGMENTATION

Table 24: Distribution of Asymmetry Resolution Status

Resolution Status	By Patient	
	n	%(N = 10)
Not Yet Resolved		
Undergoing Treatment	3	30.0%
Treatment Not Possible	1	10.0%
Refused Treatment	1	10.0%
Total	5	50.0%
Resolved*		
With Reoperation and Explantation	2	20.0%
With Reoperation Without Explantation	1	10.0%
With Non-Surgical Treatment	2	20.0%
Without Treatment	0	0.0%
Total	5	50.0%

* Includes 1 occurrence of Asymmetry that was resolved after explantation of the patient's primary study device.

CORE STUDY - AUGMENTATION

Table 25: Risk of First Occurrence of Breast Pain

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	18	464	3.7% (2.0%, 5.3%)	26	937	2.7% (1.6%, 3.7%)
6 Months	20	456	4.1% (2.3%, 5.9%)	28	922	2.9% (1.8%, 3.9%)
1 Year	21	445	4.3% (2.5%, 6.1%)	29	899	3.0% (1.9%, 4.0%)
2 Years	24	406	5.0% (3.0%, 6.9%)	32	822	3.3% (2.2%, 4.4%)

Attachment 7

CORE STUDY - AUGMENTATION

Table 26: Incidence and Prevalence of Breast Pain

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	18 (3.7%)	18 (3.7%)	493	26 (2.6%)	26 (2.6%)	985
6 Months	2 (0.4%)	8 (1.7%)	481	2 (0.2%)	10 (1.0%)	961
1 Year	1 (0.2%)	4 (0.8%)	473	1 (0.1%)	5 (0.5%)	944
2 Years	3 (0.6%)	4 (0.9%)	462	3 (0.3%)	4 (0.4%)	921

CORE STUDY - AUGMENTATION

Table 27: Time to Resolution of Breast Pain

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 5)	
Minimum	112
Median	238
Maximum	424
Resolved - Time To Resolution (N = 19)	
Minimum	1
Median	6
Maximum	189

CORE STUDY - AUGMENTATION

Table 28: Distribution of Breast Pain Resolution Status

Resolution Status	By Patient	
	n	%(N = 24)
Not Yet Resolved		
Undergoing Treatment	4	16.7%
Treatment Not Possible	0	0.0%
Refused Treatment	1	4.2%
Total	5	20.8%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	6	25.0%
Without Treatment	13	54.2%
Total	19	79.2%

CORE STUDY - AUGMENTATION

Table 29: Risk of First Occurrence of Bruising

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	5	477	1.0% (0.1%, 1.9%)	9	954	0.9% (0.3%, 1.5%)
6 Months	5	469	1.0% (0.1%, 1.9%)	9	937	0.9% (0.3%, 1.5%)
1 Year	6	457	1.2% (0.3%, 2.2%)	10	913	1.0% (0.4%, 1.7%)
2 Years	6	421	1.2% (0.3%, 2.2%)	10	839	1.0% (0.4%, 1.7%)

CORE STUDY - AUGMENTATION

Table 30: Incidence and Prevalence of Bruising

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	5 (1.0%)	5 (1.0%)	493	9 (0.9%)	9 (0.9%)	985
6 Months	0 (0.0%)	2 (0.4%)	481	0 (0.0%)	4 (0.4%)	961
1 Year	1 (0.2%)	1 (0.2%)	473	1 (0.1%)	1 (0.1%)	944
2 Years	0 (0.0%)	0 (0.0%)	462	0 (0.0%)	0 (0.0%)	921

CORE STUDY - AUGMENTATION

Table 31: Time to Resolution of Bruising

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 0)	
Minimum	.
Median	.
Maximum	.
Resolved - Time To Resolution (N = 6)	
Minimum	1
Median	26
Maximum	57

CORE STUDY - AUGMENTATION

Table 32: Distribution of Bruising Resolution Status

Resolution Status	By Patient	
	n	%(N = 6)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	0	0.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	2	33.3%
Without Treatment	4	66.7%
Total	6	100.0%

CORE STUDY - AUGMENTATION

Table 33: Risk of First Occurrence of Capsule Calcification

	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk		Number Affected	Number Remaining	Cumulative Risk	
Time	n	n	%	(95% CI)	n	n	%	(95% CI)
4 Weeks	0	481	0.0%	--	0	961	0.0%	--
6 Months	0	473	0.0%	--	0	944	0.0%	--
1 Year	0	462	0.0%	--	0	921	0.0%	--
2 Years	1	424	0.2%	(0.0%, 0.7%)	1	844	0.1%	(0.0%, 0.3%)

CORE STUDY - AUGMENTATION

Table 34: Incidence and Prevalence of Capsule Calcification

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	493	0 (0.0%)	0 (0.0%)	985
6 Months	0 (0.0%)	0 (0.0%)	481	0 (0.0%)	0 (0.0%)	961
1 Year	0 (0.0%)	0 (0.0%)	473	0 (0.0%)	0 (0.0%)	944
2 Years	1 (0.2%)	1 (0.2%)	462	1 (0.1%)	1 (0.1%)	921

CORE STUDY - AUGMENTATION

Table 35: Time to Resolution of Capsule Calcification

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 1)	
Minimum	42
Median	42
Maximum	42
Resolved - Time To Resolution (N = 0)	
Minimum	.
Median	.
Maximum	.

CORE STUDY - AUGMENTATION

Table 36: Distribution of Capsule Calcification Resolution Status

Resolution Status	By Patient	
	n	%(N = 1)
Not Yet Resolved		
Undergoing Treatment	1	100.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	1	100.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	0	0.0%
Total	0	0.0%

CORE STUDY - AUGMENTATION

Table 37: Risk of First Occurrence of Capsular Contracture

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	2	479	0.4% (0.0%, 1.0%)	4	957	0.4% (0.0%, 0.8%)
6 Months	17	459	3.5% (1.9%, 5.2%)	26	925	2.7% (1.7%, 3.7%)
1 Year	29	440	6.1% (3.9%, 8.2%)	44	890	4.6% (3.3%, 6.0%)
2 Years	32	401	6.7% (4.5%, 9.0%)	48	812	5.1% (3.7%, 6.5%)

CORE STUDY - AUGMENTATION

Table 38: Incidence and Prevalence of Capsular Contracture

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	2 (0.4%)	2 (0.4%)	493	4 (0.4%)	4 (0.4%)	985
6 Months	15 (3.1%)	17 (3.5%)	481	22 (2.3%)	26 (2.7%)	961
1 Year	12 (2.5%)	21 (4.4%)	473	18 (1.9%)	31 (3.3%)	944
2 Years	3 (0.6%)	13 (2.8%)	462	4 (0.4%)	19 (2.1%)	921

CORE STUDY - AUGMENTATION

Table 39: Time to Resolution of Capsular Contracture

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 8)	
Minimum	99
Median	494
Maximum	1086
Resolved - Time To Resolution (N = 24)*	
Minimum	1
Median	67
Maximum	727

* Includes 3 occurrences of Capsular Contracture that were resolved after explantation of the patient's primary study device.

CORE STUDY - AUGMENTATION

Table 40: Distribution of Capsular Contracture Resolution Status

Resolution Status	By Patient n	By Patient %(N = 32)
Not Yet Resolved		
Undergoing Treatment	8	25.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	8	25.0%
Resolved*		
With Reoperation and Explantation	4	12.5%
With Reoperation Without Explantation	12	37.5%
With Non-Surgical Treatment	6	18.8%
Without Treatment	2	6.3%
Total	24	75.0%

* Includes 3 occurrences of Capsular Contracture that were resolved after explantation of the patient's primary study device.

CORE STUDY - AUGMENTATION

Table 41: Risk of First Occurrence of Delayed Wound Healing

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	2	479	0.4% (0.0%, 1.0%)	3	958	0.3% (0.0%, 0.7%)
6 Months	3	470	0.6% (0.0%, 1.3%)	4	940	0.4% (0.0%, 0.8%)
1 Year	3	459	0.6% (0.0%, 1.3%)	4	917	0.4% (0.0%, 0.8%)
2 Years	3	422	0.6% (0.0%, 1.3%)	4	842	0.4% (0.0%, 0.8%)

CORE STUDY - AUGMENTATION

Table 42: Incidence and Prevalence of Delayed Wound Healing

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	2 (0.4%)	2 (0.4%)	493	3 (0.3%)	3 (0.3%)	985
6 Months	1 (0.2%)	1 (0.2%)	481	1 (0.1%)	1 (0.1%)	961
1 Year	0 (0.0%)	1 (0.2%)	473	0 (0.0%)	1 (0.1%)	944
2 Years	0 (0.0%)	1 (0.2%)	462	0 (0.0%)	1 (0.1%)	921

CORE STUDY - AUGMENTATION

Table 43: Time to Resolution of Delayed Wound Healing

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 1)	
Minimum	714
Median	714
Maximum	714
Resolved - Time To Resolution (N = 2)	
Minimum	1
Median	5
Maximum	8

CORE STUDY - AUGMENTATION

Table 44: Distribution of Delayed Wound Healing Resolution Status

Resolution Status	By Patient	
	n	%(N = 3)
Not Yet Resolved		
Undergoing Treatment	1	33.3%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	1	33.3%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	1	33.3%
With Non-Surgical Treatment	0	0.0%
Without Treatment	1	33.3%
Total	2	66.7%

CORE STUDY - AUGMENTATION

Table 45: Risk of First Occurrence of Fluid Accumulation

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	0	481	0.0% (0.0%, 0.0%)	0	961	0.0% (0.0%, 0.0%)
6 Months	1	472	0.2% (0.0%, 0.6%)	1	943	0.1% (0.0%, 0.3%)
1 Year	2	460	0.4% (0.0%, 1.0%)	2	919	0.2% (0.0%, 0.5%)
2 Years	2	422	0.4% (0.0%, 1.0%)	2	842	0.2% (0.0%, 0.5%)

CORE STUDY - AUGMENTATION

Table 46: Incidence and Prevalence of Fluid Accumulation

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	493	0 (0.0%)	0 (0.0%)	985
6 Months	1 (0.2%)	1 (0.2%)	481	1 (0.1%)	1 (0.1%)	961
1 Year	1 (0.2%)	1 (0.2%)	473	1 (0.1%)	1 (0.1%)	944
2 Years	0 (0.0%)	0 (0.0%)	462	0 (0.0%)	0 (0.0%)	921

CORE STUDY - AUGMENTATION

Table 47: Time to Resolution of Fluid Accumulation

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 0)	
Minimum	.
Median	.
Maximum	.
Resolved - Time To Resolution (N = 2)	
Minimum	1
Median	12
Maximum	23

CORE STUDY - AUGMENTATION

Table 48: Distribution of Fluid Accumulation Resolution Status

Resolution Status	By Patient	
	n	%(N = 2)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	0	0.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	1	50.0%
Without Treatment	1	50.0%
Total	2	100.0%

CORE STUDY - AUGMENTATION

Table 49: Risk of First Occurrence of Hematoma

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	4	477	0.8% (0.0%, 1.6%)	4	957	0.4% (0.0%, 0.8%)
6 Months	4	469	0.8% (0.0%, 1.6%)	4	940	0.4% (0.0%, 0.8%)
1 Year	4	458	0.8% (0.0%, 1.6%)	4	917	0.4% (0.0%, 0.8%)
2 Years	4	420	0.8% (0.0%, 1.6%)	4	840	0.4% (0.0%, 0.8%)

CORE STUDY - AUGMENTATION

Table 50: Incidence and Prevalence of Hematoma

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	4 (0.8%)	4 (0.8%)	493	4 (0.4%)	4 (0.4%)	985
6 Months	0 (0.0%)	0 (0.0%)	481	0 (0.0%)	0 (0.0%)	961
1 Year	0 (0.0%)	0 (0.0%)	473	0 (0.0%)	0 (0.0%)	944
2 Years	0 (0.0%)	0 (0.0%)	462	0 (0.0%)	0 (0.0%)	921

CORE STUDY - AUGMENTATION

Table 51: Time to Resolution of Hematoma

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 0)	
Minimum	.
Median	.
Maximum	.
Resolved - Time To Resolution (N = 4)	
Minimum	1
Median	6
Maximum	7

CORE STUDY - AUGMENTATION

Table 52: Distribution of Hematoma Resolution Status

Resolution Status	By Patient	
	n	%(N = 4)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	0	0.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	4	100.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	0	0.0%
Total	4	100.0%

CORE STUDY - AUGMENTATION

Table 53: Risk of First Occurrence of Hypertrophic Scarring

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	2	479	0.4% (0.0%, 1.0%)	3	958	0.3% (0.0%, 0.7%)
6 Months	6	467	1.2% (0.3%, 2.2%)	9	935	0.9% (0.3%, 1.5%)
1 Year	7	455	1.5% (0.4%, 2.5%)	11	910	1.1% (0.5%, 1.8%)
2 Years	8	417	1.7% (0.5%, 2.8%)	13	833	1.4% (0.6%, 2.1%)

CORE STUDY - AUGMENTATION

Table 54: Incidence and Prevalence of Hypertrophic Scarring

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	2 (0.4%)	2 (0.4%)	493	3 (0.3%)	3 (0.3%)	985
6 Months	4 (0.8%)	5 (1.0%)	481	6 (0.6%)	8 (0.8%)	961
1 Year	1 (0.2%)	5 (1.1%)	473	2 (0.2%)	9 (1.0%)	944
2 Years	1 (0.2%)	5 (1.1%)	462	2 (0.2%)	9 (1.0%)	921

CORE STUDY - AUGMENTATION

Table 55: Time to Resolution of Hypertrophic Scarring

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 2)	
Minimum	679
Median	876
Maximum	1072
Resolved - Time To Resolution (N = 6)	
Minimum	1
Median	180
Maximum	280

CORE STUDY - AUGMENTATION

Table 56: Distribution of Hypertrophic Scarring Resolution Status

Resolution Status	By Patient	
	n	%(N = 8)
Not Yet Resolved		
Undergoing Treatment	2	25.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	2	25.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	3	37.5%
With Non-Surgical Treatment	3	37.5%
Without Treatment	0	0.0%
Total	6	75.0%

CORE STUDY - AUGMENTATION

Table 57: Risk of First Occurrence of Implant Extrusion

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	0	481	0.0% (0.0%, 0.0%)	0	961	0.0% (0.0%, 0.0%)
6 Months	1	473	0.2% (0.0%, 0.6%)	1	944	0.1% (0.0%, 0.3%)
1 Year	1	462	0.2% (0.0%, 0.6%)	1	921	0.1% (0.0%, 0.3%)
2 Years	1	424	0.2% (0.0%, 0.6%)	1	844	0.1% (0.0%, 0.3%)

CORE STUDY - AUGMENTATION

Table 58: Incidence and Prevalence of Implant Extrusion

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	493	0 (0.0%)	0 (0.0%)	985
6 Months	1 (0.2%)	1 (0.2%)	481	1 (0.1%)	1 (0.1%)	961
1 Year	0 (0.0%)	0 (0.0%)	473	0 (0.0%)	0 (0.0%)	944
2 Years	0 (0.0%)	0 (0.0%)	462	0 (0.0%)	0 (0.0%)	921

CORE STUDY - AUGMENTATION

Table 59: Time to Resolution of Implant Extrusion

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 0)	
Minimum	.
Median	.
Maximum	.
Resolved - Time To Resolution (N = 1)*	
Minimum	3
Median	3
Maximum	3

* Includes 1 occurrence of Implant Extrusion that was resolved after explantation of the patient's primary study device.

CORE STUDY - AUGMENTATION

Table 60: Distribution of Implant Extrusion Resolution Status

Resolution Status	By Patient	
	n	%(N = 1)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	0	0.0%
Resolved*		
With Reoperation and Explantation	1	100.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	0	0.0%
Total	1	100.0%

* Includes 1 occurrence of Implant Extrusion that was resolved after explantation of the patient's primary study device.

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Table 61: Risk of First Occurrence of Implant Malposition

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	3	478	0.6% (0.0%, 1.3%)	4	957	0.4% (0.0%, 0.8%)
6 Months	8	466	1.7% (0.5%, 2.8%)	12	934	1.2% (0.5%, 2.0%)
1 Year	10	453	2.1% (0.8%, 3.4%)	15	908	1.6% (0.8%, 2.4%)
2 Years	12	416	2.5% (1.1%, 4.0%)	18	832	1.9% (1.0%, 2.8%)

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Table 62: Incidence and Prevalence of Implant Malposition

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	3 (0.6%)	3 (0.6%)	493	4 (0.4%)	4 (0.4%)	985
6 Months	5 (1.0%)	8 (1.7%)	481	8 (0.8%)	12 (1.2%)	961
1 Year	2 (0.4%)	5 (1.1%)	473	3 (0.3%)	7 (0.7%)	944
2 Years	2 (0.4%)	6 (1.3%)	462	3 (0.3%)	7 (0.8%)	921

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Table 63: Time to Resolution of Implant Malposition

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 2)	
Minimum	104
Median	385
Maximum	666
Resolved - Time To Resolution (N = 10)	
Minimum	1
Median	70
Maximum	666

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Table 64: Distribution of Implant Malposition Resolution Status

Resolution Status	By Patient	
	n	%(N = 12)
Not Yet Resolved		
Undergoing Treatment	2	16.7%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	2	16.7%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	6	50.0%
With Non-Surgical Treatment	2	16.7%
Without Treatment	2	16.7%
Total	10	83.3%

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Table 65: Risk of First Occurrence of Implant Palpability

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	1	480	0.2% (0.0%, 0.6%)	1	960	0.1% (0.0%, 0.3%)
6 Months	3	470	0.6% (0.0%, 1.3%)	4	940	0.4% (0.0%, 0.8%)
1 Year	3	459	0.6% (0.0%, 1.3%)	4	917	0.4% (0.0%, 0.8%)
2 Years	3	422	0.6% (0.0%, 1.3%)	4	841	0.4% (0.0%, 0.8%)

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Table 66: Incidence and Prevalence of Implant Palpability

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	1 (0.2%)	1 (0.2%)	493	1 (0.1%)	1 (0.1%)	985
6 Months	2 (0.4%)	3 (0.6%)	481	3 (0.3%)	4 (0.4%)	961
1 Year	0 (0.0%)	3 (0.6%)	473	0 (0.0%)	4 (0.4%)	944
2 Years	0 (0.0%)	3 (0.6%)	462	0 (0.0%)	4 (0.4%)	921

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Table 67: Time to Resolution of Implant Palpability

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 2)	
Minimum	579
Median	801
Maximum	1022
Resolved - Time To Resolution (N = 1)	
Minimum	375
Median	375
Maximum	375

CORE STUDY - AUGMENTATION

Table 68: Distribution of Implant Palpability Resolution Status

Resolution Status	By Patient	
	n	%(N = 3)
Not Yet Resolved		
Undergoing Treatment	1	33.3%
Treatment Not Possible	1	33.3%
Refused Treatment	0	0.0%
Total	2	66.7%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	1	33.3%
Total	1	33.3%

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Table 69: Risk of First Occurrence of Implant Visibility

	By Patient				By Implant			
	Number Affected	Number Remaining		Cumulative Risk	Number Affected	Number Remaining		Cumulative Risk
Time	n	n	%	(95% CI)	n	n	%	(95% CI)
4 Weeks	0	481	0.0%	--	0	961	0.0%	--
6 Months	0	473	0.0%	--	0	944	0.0%	--
1 Year	0	462	0.0%	--	0	921	0.0%	--
2 Years	0	424	0.0%	--	0	844	0.0%	--

CORE STUDY - AUGMENTATION

Table 70: Incidence and Prevalence of Implant Visibility

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	493	0 (0.0%)	0 (0.0%)	985
6 Months	0 (0.0%)	0 (0.0%)	481	0 (0.0%)	0 (0.0%)	961
1 Year	0 (0.0%)	0 (0.0%)	473	0 (0.0%)	0 (0.0%)	944
2 Years	0 (0.0%)	0 (0.0%)	462	0 (0.0%)	0 (0.0%)	921

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Table 71: Time to Resolution of Implant Visibility

THERE WAS NO IMPLANT VISIBILITY OBSERVED AMONG AUGMENTATION PATIENTS

CORE STUDY - AUGMENTATION

Table 72: Distribution of Implant Visibility Resolution Status

THERE WAS NO IMPLANT VISIBILITY OBSERVED AMONG AUGMENTATION PATIENTS

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Table 73: Risk of First Occurrence of Infection

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	0	481	0.0% --	0	961	0.0% --
6 Months	0	473	0.0% --	0	944	0.0% --
1 Year	0	462	0.0% --	0	921	0.0% --
2 Years	0	424	0.0% --	0	844	0.0% --

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Table 74: Incidence and Prevalence of Infection

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	493	0 (0.0%)	0 (0.0%)	985
6 Months	0 (0.0%)	0 (0.0%)	481	0 (0.0%)	0 (0.0%)	961
1 Year	0 (0.0%)	0 (0.0%)	473	0 (0.0%)	0 (0.0%)	944
2 Years	0 (0.0%)	0 (0.0%)	462	0 (0.0%)	0 (0.0%)	921

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Table 75: Time to Resolution of Infection

THERE WAS NO INFECTION OBSERVED AMONG AUGMENTATION PATIENTS

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Table 76: Distribution of Infection Resolution Status

THERE WAS NO INFECTION OBSERVED AMONG AUGMENTATION PATIENTS

CORE STUDY - AUGMENTATION

Table 77: Risk of First Occurrence of Irritation

Time	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk		Number Affected	Number Remaining	Cumulative Risk	
	n	n	%	(95% CI)	n	n	%	(95% CI)
4 Weeks	0	481	0.0%	--	0	961	0.0%	--
6 Months	0	473	0.0%	--	0	944	0.0%	--
1 Year	0	462	0.0%	--	0	921	0.0%	--
2 Years	0	424	0.0%	--	0	844	0.0%	--

CORE STUDY - AUGMENTATION

Table 78: Incidence and Prevalence of Irritation

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	493	0 (0.0%)	0 (0.0%)	985
6 Months	0 (0.0%)	0 (0.0%)	481	0 (0.0%)	0 (0.0%)	961
1 Year	0 (0.0%)	0 (0.0%)	473	0 (0.0%)	0 (0.0%)	944
2 Years	0 (0.0%)	0 (0.0%)	462	0 (0.0%)	0 (0.0%)	921

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Table 79: Time to Resolution of Irritation

THERE WAS NO IRRITATION OBSERVED AMONG AUGMENTATION PATIENTS

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Table 80: Distribution of Irritation Resolution Status

THERE WAS NO IRRITATION OBSERVED AMONG AUGMENTATION PATIENTS

Attachment 7

CORE STUDY - AUGMENTATION

Table 81: Risk of First Occurrence of Loss of Nipple Sensation

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	9	472	1.8% (0.7%, 3.1%)	14	947	1.4% (0.7%, 2.2%)
6 Months	13	460	2.7% (1.2%, 4.1%)	20	924	2.1% (1.2%, 3.0%)
1 Year	14	448	2.9% (1.4%, 4.4%)	21	900	2.2% (1.3%, 3.1%)
2 Years	15	410	3.1% (1.6%, 4.7%)	23	823	2.4% (1.4%, 3.4%)

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Table 82: Incidence and Prevalence of Loss of Nipple Sensation

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	9 (1.8%)	9 (1.8%)	493	14 (1.4%)	14 (1.4%)	985
6 Months	4 (0.8%)	12 (2.5%)	481	6 (0.6%)	19 (2.0%)	961
1 Year	1 (0.2%)	8 (1.7%)	473	1 (0.1%)	11 (1.2%)	944
2 Years	1 (0.2%)	4 (0.9%)	462	2 (0.2%)	5 (0.5%)	921

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Table 83: Time to Resolution of Loss of Nipple Sensation

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 3)	
Minimum	432
Median	676
Maximum	714
Resolved - Time To Resolution (N = 12)	
Minimum	11
Median	107
Maximum	362

CORE STUDY - AUGMENTATION

Table 84: Distribution of Loss of Nipple Sensation Resolution Status

Resolution Status	By Patient	
	n	%(N = 15)
Not Yet Resolved		
Undergoing Treatment	1	6.7%
Treatment Not Possible	2	13.3%
Refused Treatment	0	0.0%
Total	3	20.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	12	80.0%
Total	12	80.0%

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Table 85: Risk of First Occurrence of Loss of Skin Sensation

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	6	475	1.2% (0.3%, 2.2%)	10	951	1.0% (0.4%, 1.7%)
6 Months	6	467	1.2% (0.3%, 2.2%)	10	934	1.0% (0.4%, 1.7%)
1 Year	6	456	1.2% (0.3%, 2.2%)	10	911	1.0% (0.4%, 1.7%)
2 Years	6	418	1.2% (0.3%, 2.2%)	10	834	1.0% (0.4%, 1.7%)

CORE STUDY - AUGMENTATION

Table 86: Incidence and Prevalence of Loss of Skin Sensation

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	6 (1.2%)	6 (1.2%)	493	10 (1.0%)	10 (1.0%)	985
6 Months	0 (0.0%)	6 (1.2%)	481	0 (0.0%)	10 (1.0%)	961
1 Year	0 (0.0%)	2 (0.4%)	473	0 (0.0%)	3 (0.3%)	944
2 Years	0 (0.0%)	1 (0.2%)	462	0 (0.0%)	1 (0.1%)	921

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Table 87: Time to Resolution of Loss of Skin Sensation

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 1)	
Minimum	739
Median	739
Maximum	739
Resolved - Time To Resolution (N = 5)	
Minimum	28
Median	58
Maximum	201

CORE STUDY - AUGMENTATION

Table 88: Distribution of Loss of Skin Sensation Resolution Status

Resolution Status	By Patient	
	n	%(N = 6)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	1	16.7%
Refused Treatment	0	0.0%
Total	1	16.7%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	1	16.7%
Without Treatment	4	66.7%
Total	5	83.3%

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Table 89: Risk of First Occurrence of Lymphadenopathy

	By Patient				By Implant			
	Number Affected	Number Remaining		Cumulative Risk	Number Affected	Number Remaining		Cumulative Risk
Time	n	n	%	(95% CI)	n	n	%	(95% CI)
4 Weeks	0	481	0.0%	--	0	961	0.0%	--
6 Months	0	473	0.0%	--	0	944	0.0%	--
1 Year	0	462	0.0%	--	0	921	0.0%	--
2 Years	1	423	0.2%	(0.0%, 0.7%)	1	843	0.1%	(0.0%, 0.3%)

CORE STUDY - AUGMENTATION

Table 90: Incidence and Prevalence of Lymphadenopathy

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	493	0 (0.0%)	0 (0.0%)	985
6 Months	0 (0.0%)	0 (0.0%)	481	0 (0.0%)	0 (0.0%)	961
1 Year	0 (0.0%)	0 (0.0%)	473	0 (0.0%)	0 (0.0%)	944
2 Years	1 (0.2%)	1 (0.2%)	462.	1 (0.1%)	1 (0.1%)	921

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Table 91 : Time to Resolution of Lymphadenopathy

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 1)	
Minimum	614
Median	614
Maximum	614
Resolved - Time To Resolution (N = 0)	
Minimum	.
Median	.
Maximum	.

CORE STUDY - AUGMENTATION

Table 92: Distribution of Lymphadenopathy Resolution Status

Resolution Status	By Patient	
	n	%(N = 1)
Not Yet Resolved		
Undergoing Treatment	1	100.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	1	100.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	0	0.0%
Total	0	0.0%

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Table 93: Risk of First Occurrence of Lymphedema

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	0	481	0.0% --	0	961	0.0% --
6 Months	1	472	0.2% (0.0%, 0.6%)	1	943	0.1% (0.0%, 0.3%)
1 Year	1	461	0.2% (0.0%, 0.6%)	1	920	0.1% (0.0%, 0.3%)
2 Years	1	423	0.2% (0.0%, 0.6%)	1	844	0.1% (0.0%, 0.3%)

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Table 94: Incidence and Prevalence of Lymphedema

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	493	0 (0.0%)	0 (0.0%)	985
6 Months	1 (0.2%)	1 (0.2%)	481	1 (0.1%)	1 (0.1%)	961
1 Year	0 (0.0%)	1 (0.2%)	473	0 (0.0%)	1 (0.1%)	944
2 Years	0 (0.0%)	0 (0.0%)	462	0 (0.0%)	0 (0.0%)	921

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Table 95: Time to Resolution of Lymphedema

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 0)	
Minimum	.
Median	.
Maximum	.
Resolved - Time To Resolution (N = 1)	
Minimum	17
Median	17
Maximum	17

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Table 96: Distribution of Lymphedema Resolution Status

Resolution Status	By Patient	
	n	%(N = 1)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	0	0.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	1	100.0%
Total	1	100.0%

CORE STUDY - AUGMENTATION

Table 97: Risk of First Occurrence of Nipple Hypersensitivity

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	2	479	0.4% (0.0%, 1.0%)	4	957	0.4% (0.0%, 0.8%)
6 Months	2	471	0.4% (0.0%, 1.0%)	4	940	0.4% (0.0%, 0.8%)
1 Year	2	460	0.4% (0.0%, 1.0%)	4	917	0.4% (0.0%, 0.8%)
2 Years	2	422	0.4% (0.0%, 1.0%)	4	840	0.4% (0.0%, 0.8%)

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Table 98: Incidence and Prevalence of Nipple Hypersensitivity

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	2 (0.4%)	2 (0.4%)	493	4 (0.4%)	4 (0.4%)	985
6 Months	0 (0.0%)	1 (0.2%)	481	0 (0.0%)	2 (0.2%)	961
1 Year	0 (0.0%)	0 (0.0%)	473	0 (0.0%)	0 (0.0%)	944
2 Years	0 (0.0%)	0 (0.0%)	462	0 (0.0%)	0 (0.0%)	921

CORE STUDY - AUGMENTATION

Table 99: Time to Resolution of Nipple Hypersensitivity

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 0)	
Minimum	.
Median	.
Maximum	.
Resolved - Time To Resolution (N = 2)	
Minimum	14
Median	49
Maximum	84

CORE STUDY - AUGMENTATION

Table 100: Distribution of Nipple Hypersensitivity Resolution Status

Resolution Status	By Patient	
	n	%(N = 2)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	0	0.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	2	100.0%
Total	2	100.0%

CORE STUDY - AUGMENTATION

Table 101: Risk of First Occurrence of Nipple Paresthesia

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	2	479	0.4% (0.0%, 1.0%)	3	958	0.3% (0.0%, 0.7%)
6 Months	2	471	0.4% (0.0%, 1.0%)	3	941	0.3% (0.0%, 0.7%)
1 Year	2	461	0.4% (0.0%, 1.0%)	3	920	0.3% (0.0%, 0.7%)
2 Years	2	424	0.4% (0.0%, 1.0%)	3	844	0.3% (0.0%, 0.7%)

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Table 102: Incidence and Prevalence of Nipple Paresthesia

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	2 (0.4%)	2 (0.4%)	493	3 (0.3%)	3 (0.3%)	985
6 Months	0 (0.0%)	2 (0.4%)	481	0 (0.0%)	3 (0.3%)	961
1 Year	0 (0.0%)	1 (0.2%)	473	0 (0.0%)	2 (0.2%)	944
2 Years	0 (0.0%)	0 (0.0%)	462	0 (0.0%)	0 (0.0%)	921

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Table 103: Time to Resolution of Nipple Paresthesia

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 1)	
Minimum	216
Median	216
Maximum	216
Resolved - Time To Resolution (N = 1)	
Minimum	21
Median	21
Maximum	21

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Table 104: Distribution of Nipple Paresthesia Resolution Status

Resolution Status	By Patient	
	n	%(N = 2)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	1	50.0%
Refused Treatment	0	0.0%
Total	1	50.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	1	50.0%
Total	1	50.0%

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Table 105: Risk of First Occurrence of Other Abnormal Scarring

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	0	481	0.0% (0.0%, 0.0%)	0	961	0.0% (0.0%, 0.0%)
6 Months	0	473	0.0% (0.0%, 0.0%)	0	944	0.0% (0.0%, 0.0%)
1 Year	1	461	0.2% (0.0%, 0.6%)	1	920	0.1% (0.0%, 0.3%)
2 Years	4	420	0.9% (0.0%, 1.8%)	6	838	0.7% (0.1%, 1.2%)

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Table 106: Incidence and Prevalence of Other Abnormal Scarring

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	493	0 (0.0%)	0 (0.0%)	985
6 Months	0 (0.0%)	0 (0.0%)	481	0 (0.0%)	0 (0.0%)	961
1 Year	1 (0.2%)	1 (0.2%)	473	1 (0.1%)	1 (0.1%)	944
2 Years	3 (0.6%)	4 (0.9%)	462	5 (0.5%)	6 (0.7%)	921

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Table 107: Time to Resolution of Other Abnormal Scarring

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 1)	
Minimum	503
Median	503
Maximum	503
Resolved - Time To Resolution (N = 3)	
Minimum	36
Median	67
Maximum	77

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Table 108: Distribution of Other Abnormal Scarring Resolution Status

Resolution Status	By Patient	
	n	%(N = 4)
Not Yet Resolved		
Undergoing Treatment	1	25.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	1	25.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	2	50.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	1	25.0%
Total	3	75.0%

CORE STUDY - AUGMENTATION

Table 109: Risk of First Occurrence of Other Nipple Related Observation

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	3	478	0.6% (0.0%, 1.3%)	5	956	0.5% (0.1%, 1.0%)
6 Months	6	467	1.2% (0.3%, 2.2%)	9	935	0.9% (0.3%, 1.5%)
1 Year	6	456	1.2% (0.3%, 2.2%)	9	912	0.9% (0.3%, 1.5%)
2 Years	7	418	1.5% (0.4%, 2.6%)	11	835	1.2% (0.5%, 1.8%)

CORE STUDY - AUGMENTATION

Table 110: Incidence and Prevalence of Other Nipple Related Observation

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	3 (0.6%)	3 (0.6%)	493	5 (0.5%)	5 (0.5%)	985
6 Months	3 (0.6%)	6 (1.2%)	481	4 (0.4%)	9 (0.9%)	961
1 Year	0 (0.0%)	4 (0.8%)	473	0 (0.0%)	6 (0.6%)	944
2 Years	1 (0.2%)	3 (0.6%)	462	2 (0.2%)	5 (0.5%)	921

CORE STUDY - AUGMENTATION

Table 111: Time to Resolution of Other Nipple Related Observation

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 1)	
Minimum	135
Median	135
Maximum	135
Resolved - Time To Resolution (N = 6)	
Minimum	25
Median	172
Maximum	351

CORE STUDY - AUGMENTATION

Table 112: Distribution of Other Nipple Related Observation Resolution Status

Resolution Status	By Patient	
	n	%(N = 7)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	1	14.3%
Total	1	14.3%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	3	42.9%
Without Treatment	3	42.9%
Total	6	85.7%

CORE STUDY - AUGMENTATION

Table 113: Risk of First Occurrence of Pneumothorax

	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk		Number Affected	Number Remaining	Cumulative Risk	
Time	n	n	%	(95% CI)	n	n	%	(95% CI)
4 Weeks	0	481	0.0%	--	0	961	0.0%	--
6 Months	0	473	0.0%	--	0	944	0.0%	--
1 Year	0	462	0.0%	--	0	921	0.0%	--
2 Years	0	424	0.0%	--	0	844	0.0%	--

CORE STUDY - AUGMENTATION

Table 114: Incidence and Prevalence of Pneumothorax

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	493	0 (0.0%)	0 (0.0%)	985
6 Months	0 (0.0%)	0 (0.0%)	481	0 (0.0%)	0 (0.0%)	961
1 Year	0 (0.0%)	0 (0.0%)	473	0 (0.0%)	0 (0.0%)	944
2 Years	0 (0.0%)	0 (0.0%)	462	0 (0.0%)	0 (0.0%)	921

CORE STUDY - AUGMENTATION

Table 115: Time to Resolution of Pneumothorax

THERE WAS NO PNEUMOTHORAX OBSERVED AMONG AUGMENTATION PATIENTS

CORE STUDY - AUGMENTATION

Table 116: Distribution of Pneumothorax Resolution Status

THERE WAS NO PNEUMOTHORAX OBSERVED AMONG AUGMENTATION PATIENTS

CORE STUDY - AUGMENTATION

Table 117: Risk of First Occurrence of Ptosis

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	0	481	0.0% (0.0%, 0.0%)	0	961	0.0% (0.0%, 0.0%)
6 Months	1	473	0.2% (0.0%, 0.6%)	2	944	0.2% (0.0%, 0.5%)
1 Year	3	460	0.6% (0.0%, 1.3%)	6	917	0.6% (0.1%, 1.1%)
2 Years	6	420	1.3% (0.3%, 2.4%)	12	836	1.3% (0.6%, 2.1%)

CORE STUDY - AUGMENTATION

Table 118: Incidence and Prevalence of Ptosis

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	493	0 (0.0%)	0 (0.0%)	985
6 Months	1 (0.2%)	1 (0.2%)	481	2 (0.2%)	2 (0.2%)	961
1 Year	2 (0.4%)	2 (0.4%)	473	4 (0.4%)	4 (0.4%)	944
2 Years	3 (0.6%)	5 (1.1%)	462	6 (0.7%)	10 (1.1%)	921

CORE STUDY - AUGMENTATION

Table 119: Time to Resolution of Ptosis

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 2)	
Minimum	42
Median	310
Maximum	577
Resolved - Time To Resolution (N = 4)	
Minimum	1
Median	21
Maximum	190

CORE STUDY - AUGMENTATION

Table 120 : Distribution of Ptosis Resolution Status

Resolution Status	By Patient	
	n	%(N = 6)
Not Yet Resolved		
Undergoing Treatment	2	33.3%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	2	33.3%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	2	33.3%
With Non-Surgical Treatment	2	33.3%
Without Treatment	0	0.0%
Total	4	66.7%

CORE STUDY - AUGMENTATION

Table 121: Risk of First Occurrence of Redness

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	4	477	0.8% (0.0%, 1.6%)	6	955	0.6% (0.1%, 1.1%)
6 Months	4	469	0.8% (0.0%, 1.6%)	6	938	0.6% (0.1%, 1.1%)
1 Year	4	458	0.8% (0.0%, 1.6%)	6	915	0.6% (0.1%, 1.1%)
2 Years	4	420	0.8% (0.0%, 1.6%)	6	838	0.6% (0.1%, 1.1%)

CORE STUDY - AUGMENTATION

Table 122: Incidence and Prevalence of Redness

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	4 (0.8%)	4 (0.8%)	493	6 (0.6%)	6 (0.6%)	985
6 Months	0 (0.0%)	1 (0.2%)	481	0 (0.0%)	2 (0.2%)	961
1 Year	0 (0.0%)	0 (0.0%)	473	0 (0.0%)	0 (0.0%)	944
2 Years	0 (0.0%)	0 (0.0%)	462	0 (0.0%)	0 (0.0%)	921

CORE STUDY - AUGMENTATION

Table 123: Time to Resolution of Redness

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 0)	
Minimum	.
Median	.
Maximum	.
Resolved - Time To Resolution (N = 4)	
Minimum	7
Median	9
Maximum	63

CORE STUDY - AUGMENTATION

Table 124: Distribution of Redness Resolution Status

Resolution Status	By Patient	
	n	%(N = 4)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	0	0.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	3	75.0%
Without Treatment	1	25.0%
Total	4	100.0%

CORE STUDY - AUGMENTATION

Table 125: Risk of First Occurrence of Seroma

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	1	480	0.2% (0.0%; 0.6%)	1	960	0.1% (0.0%, 0.3%)
6 Months	3	470	0.6% (0.0%, 1.3%)	4	940	0.4% (0.0%, 0.8%)
1 Year	3	459	0.6% (0.0%, 1.3%)	4	917	0.4% (0.0%, 0.8%)
2 Years	3	422	0.6% (0.0%, 1.3%)	4	842	0.4% (0.0%, 0.8%)

CORE STUDY - AUGMENTATION

Table 126: Incidence and Prevalence of Seroma

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	1 (0.2%)	1 (0.2%)	493	1 (0.1%)	1 (0.1%)	985
6 Months	2 (0.4%)	3 (0.6%)	481	3 (0.3%)	4 (0.4%)	961
1 Year	0 (0.0%)	0 (0.0%)	473	0 (0.0%)	0 (0.0%)	944
2 Years	0 (0.0%)	0 (0.0%)	462	0 (0.0%)	0 (0.0%)	921

CORE STUDY - AUGMENTATION

Table 127: Time to Resolution of Seroma

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 0)	
Minimum	.
Median	.
Maximum	.
Resolved - Time To Resolution (N = 3)	
Minimum	14
Median	42
Maximum	84

CORE STUDY - AUGMENTATION

Table 128: Distribution of Seroma Resolution Status

Resolution Status	By Patient	
	n	%(N = 3)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	0	0.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	2	66.7%
Without Treatment	1	33.3%
Total	3	100.0%

CORE STUDY - AUGMENTATION

Table 129: Risk of First Occurrence of Skin Hypersensitivity

	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk		Number Affected	Number Remaining	Cumulative Risk	
Time	n	n	%	(95% CI)	n	n	%	(95% CI)
4 Weeks	0	481	0.0%	--	0	961	0.0%	--
6 Months	0	473	0.0%	--	0	944	0.0%	--
1 Year	0	462	0.0%	--	0	921	0.0%	--
2 Years	0	424	0.0%	--	0	844	0.0%	--

CORE STUDY - AUGMENTATION

Table 130: Incidence and Prevalence of Skin Hypersensitivity

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	493	0 (0.0%)	0 (0.0%)	985
6 Months	0 (0.0%)	0 (0.0%)	481	0 (0.0%)	0 (0.0%)	961
1 Year	0 (0.0%)	0 (0.0%)	473	0 (0.0%)	0 (0.0%)	944
2 Years	0 (0.0%)	0 (0.0%)	462	0 (0.0%)	0 (0.0%)	921

CORE STUDY - AUGMENTATION

Table 131: Time to Resolution of Skin Hypersensitivity

THERE WAS NO SKIN HYPERSENSITIVITY OBSERVED AMONG AUGMENTATION PATIENTS

CORE STUDY - AUGMENTATION

Table 132: Distribution of Skin Hypersensitivity Resolution Status

THERE WAS NO SKIN HYPERSENSITIVITY OBSERVED AMONG AUGMENTATION PATIENTS

CORE STUDY - AUGMENTATION

Table 133: Risk of First Occurrence of Skin Paresthesia

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	1	480	0.2% (0.0%, 0.6%)	1	960	0.1% (0.0%, 0.3%)
6 Months	1	472	0.2% (0.0%, 0.6%)	1	943	0.1% (0.0%, 0.3%)
1 Year	2	460	0.4% (0.0%, 1.0%)	3	918	0.3% (0.0%, 0.7%)
2 Years	2	423	0.4% (0.0%, 1.0%)	3	842	0.3% (0.0%, 0.7%)

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Table 134: Incidence and Prevalence of Skin Paresthesia

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	1 (0.2%)	1 (0.2%)	493	1 (0.1%)	1 (0.1%)	985
6 Months	0 (0.0%)	1 (0.2%)	481	0 (0.0%)	1 (0.1%)	961
1 Year	1 (0.2%)	1 (0.2%)	473	2 (0.2%)	2 (0.2%)	944
2 Years	0 (0.0%)	0 (0.0%)	462	0 (0.0%)	0 (0.0%)	921

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Table 135: Time to Resolution of Skin Paresthesia

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 0)	
Minimum	.
Median	.
Maximum	.
Resolved - Time To Resolution (N = 2)	
Minimum	1
Median	11
Maximum	21

CORE STUDY - AUGMENTATION

Table 136: Distribution of Skin Paresthesia Resolution Status

Resolution Status	By Patient	
	n	%(N = 2)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	0	0.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	2	100.0%
Total	2	100.0%

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Table 137: Risk of First Occurrence of Skin Rash

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	5	476	1.0% (0.1%, 1.9%)	10	951	1.0% (0.4%, 1.7%)
6 Months	8	465	1.6% (0.5%, 2.8%)	15	930	1.5% (0.8%, 2.3%)
1 Year	8	454	1.6% (0.5%, 2.8%)	15	907	1.5% (0.8%, 2.3%)
2 Years	8	417	1.6% (0.5%, 2.8%)	15	832	1.5% (0.8%, 2.3%)

CORE STUDY - AUGMENTATION

Table 138: Incidence and Prevalence of Skin Rash

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	5 (1.0%)	5 (1.0%)	493	10 (1.0%)	10 (1.0%)	985
6 Months	3 (0.6%)	5 (1.0%)	481	5 (0.5%)	9 (0.9%)	961
1 Year	0 (0.0%)	0 (0.0%)	473	0 (0.0%)	0 (0.0%)	944
2 Years	0 (0.0%)	0 (0.0%)	462	0 (0.0%)	0 (0.0%)	921

CORE STUDY - AUGMENTATION

Table 139: Time to Resolution of Skin Rash

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 0)	
Minimum	.
Median	.
Maximum	.
Resolved - Time To Resolution (N = 8)*	
Minimum	1
Median	16
Maximum	74

* Includes 1 occurrence of Skin Rash that was resolved after explantation of the patient's primary study device.

CORE STUDY - AUGMENTATION

Table 140: Distribution of Skin Rash Resolution Status

Resolution Status	By Patient n	By Patient %(N = 8)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	0	0.0%
Resolved*		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	8	100.0%
Without Treatment	0	0.0%
Total	8	100.0%

* Includes 1 occurrence of Skin Rash that was resolved after explantation of the patient's primary study device.

CORE STUDY - AUGMENTATION

Table 141: Risk of First Occurrence of Swelling

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	29	453	5.9% (3.8%, 8.0%)	49	914	5.0% (3.6%, 6.4%)
6 Months	30	445	6.1% (4.0%, 8.2%)	50	898	5.1% (3.7%, 6.5%)
1 Year	33	431	6.8% (4.5%, 9.0%)	55	870	5.6% (4.2%, 7.1%)
2 Years	33	397	6.8% (4.5%, 9.0%)	55	800	5.6% (4.2%, 7.1%)

CORE STUDY - AUGMENTATION

Table 142: Incidence and Prevalence of Swelling

Time	By Patient			By Implant		
	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	29 (5.9%)	29 (5.9%)	493	49 (5.0%)	49 (5.0%)	985
6 Months	1 (0.2%)	14 (2.9%)	481	1 (0.1%)	21 (2.2%)	961
1 Year	3 (0.6%)	6 (1.3%)	473	5 (0.5%)	9 (1.0%)	944
2 Years	0 (0.0%)	3 (0.6%)	462	0 (0.0%)	3 (0.3%)	921

CORE STUDY - AUGMENTATION

Table 143: Time to Resolution of Swelling

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 3)	
Minimum	560
Median	806
Maximum	1099
Resolved - Time To Resolution (N = 30)	
Minimum	1
Median	15
Maximum	196

CORE STUDY - AUGMENTATION

Table 144: Distribution of Swelling Resolution Status

Resolution Status	By Patient	
	n	%(N = 33)
Not Yet Resolved		
Undergoing Treatment	3	9.1%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	3	9.1%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	5	15.2%
Without Treatment	25	75.8%
Total	30	90.9%

CORE STUDY - AUGMENTATION

Table 145: Risk of First Occurrence of Tissue or Skin Necrosis

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	1	480	0.2% (0.0%, 0.6%)	1	960	0.1% (0.0%, 0.3%)
6 Months	1	472	0.2% (0.0%, 0.6%)	1	943	0.1% (0.0%, 0.3%)
1 Year	1	461	0.2% (0.0%, 0.6%)	1	920	0.1% (0.0%, 0.3%)
2 Years	1	423	0.2% (0.0%, 0.6%)	1	843	0.1% (0.0%, 0.3%)

CORE STUDY - AUGMENTATION

Table 146: Incidence and Prevalence of Tissue or Skin Necrosis

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	1 (0.2%)	1 (0.2%)	493	1 (0.1%)	1 (0.1%)	985
6 Months	0 (0.0%)	1 (0.2%)	481	0 (0.0%)	1 (0.1%)	961
1 Year	0 (0.0%)	0 (0.0%)	473	0 (0.0%)	0 (0.0%)	944
2 Years	0 (0.0%)	0 (0.0%)	462	0 (0.0%)	0 (0.0%)	921

CORE STUDY - AUGMENTATION

Table 147: Time to Resolution of Tissue or Skin Necrosis

	Measurement in Days
	By Patient
Resolution	
Not Yet Resolved - Elapsed Treatment Time (N = 0)	
Minimum	.
Median	.
Maximum	.
Resolved - Time To Resolution (N = 1)	
Minimum	29
Median	29
Maximum	29

CORE STUDY - AUGMENTATION

Table 148: Distribution of Tissue or Skin Necrosis Resolution Status

Resolution Status	By Patient	
	n	%(N = 1)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	0	0.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	1	100.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	0	0.0%
Total	1	100.0%

CORE STUDY - AUGMENTATION

Table 149: Risk of First Occurrence of Wrinkling / Rippling

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	0	481	0.0% --	0	961	0.0% --
6 Months	0	473	0.0% (0.0%, 0.0%)	0	944	0.0% (0.0%, 0.0%)
1 Year	1	461	0.2% (0.0%, 0.6%)	2	919	0.2% (0.0%, 0.5%)
2 Years	1	423	0.2% (0.0%, 0.6%)	2	842	0.2% (0.0%, 0.5%)

CORE STUDY - AUGMENTATION

Table 150: Incidence and Prevalence of Wrinkling / Rippling

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	493	0 (0.0%)	0 (0.0%)	985
6 Months	0 (0.0%)	0 (0.0%)	481	0 (0.0%)	0 (0.0%)	961
1 Year	1 (0.2%)	1 (0.2%)	473	2 (0.2%)	2 (0.2%)	944
2 Years	0 (0.0%)	1 (0.2%)	462	0 (0.0%)	2 (0.2%)	921

CORE STUDY - AUGMENTATION

Table 151: Time to Resolution of Wrinkling / Rippling

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 1)	
Minimum	931
Median	931
Maximum	931
Resolved - Time To Resolution (N = 0)	
Minimum	.
Median	.
Maximum	.

CORE STUDY - AUGMENTATION

Table 152: Distribution of Wrinkling / Rippling Resolution Status

Resolution Status	By Patient	
	n	%(N = 1)
Not Yet Resolved		
Undergoing Treatment	0	0.0%
Treatment Not Possible	1	100.0%
Refused Treatment	0	0.0%
Total	1	100.0%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	0	0.0%
Total	0	0.0%

CORE STUDY - AUGMENTATION

Table 153: Risk of First Occurrence of Other Complications

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	1	480	0.2% (0.0%, 0.6%)	1	960	0.1% (0.0%, 0.3%)
6 Months	1	472	0.2% (0.0%, 0.6%)	1	943	0.1% (0.0%, 0.3%)
1 Year	3	459	0.6% (0.0%, 1.4%)	4	917	0.4% (0.0%, 0.8%)
2 Years	3	422	0.6% (0.0%, 1.4%)	4	841	0.4% (0.0%, 0.8%)

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Table 153 (Cont.): Risk of First Occurrence of Other Complications

Other Complications Specified (N = 4)

Pt Seq#	Other Complications Specified
001*	REDUNDANT SKIN LAXITY
001*	REDUNDANT SKIN LAXITY
002	COMP.ON INCISION LINE
003	DIMPLING TO INCISION(R)

* Both the patient's left and right breasts experienced the same complication.

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Table 154: Incidence and Prevalence of Other Complications

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	1 (0.2%)	1 (0.2%)	493	1 (0.1%)	1 (0.1%)	985
6 Months	0 (0.0%)	1 (0.2%)	481	0 (0.0%)	1 (0.1%)	961
1 Year	2 (0.4%)	3 (0.6%)	473	3 (0.3%)	4 (0.4%)	944
2 Years	0 (0.0%)	1 (0.2%)	462	0 (0.0%)	1 (0.1%)	921

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Table 155: Time to Resolution of Other Complications

Resolution	Measurement in Days By Patient
Not Yet Resolved - Elapsed Treatment Time (N = 1)	
Minimum	714
Median	714
Maximum	714
Resolved - Time To Resolution (N = 2)	
Minimum	57
Median	82
Maximum	106

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Table 156: Distribution of Other Complications Resolution Status

Resolution Status	By Patient	
	n	%(N = 3)
Not Yet Resolved		
Undergoing Treatment	1	33.3%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	1	33.3%
Resolved		
With Reoperation and Explantation	0	0.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	2	66.7%
Without Treatment	0	0.0%
Total	2	66.7%

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Table 157: Worst Case Severity Levels of Complications Through 2 Years

	Patients	Severity Level* (Allowable Range 1 - 5)						Descriptive Statistics	
		Very Mild	Mild	Moderate	Severe	Very Severe			
Complication	N	%	%	%	%	%		Mean	SD
Asymmetry	34	32.4%	38.2%	20.6%	2.9%	5.9%		2.1	1.1
Breast Pain	59	27.1%	32.2%	25.4%	5.1%	10.2%		2.4	1.2
Bruising	42	26.2%	59.5%	11.9%	0.0%	2.4%		1.9	0.8
Capsule Calcification	1	0.0%	0.0%	0.0%	0.0%	100.0%		5.0	N/A**
Capsular Contracture***	67	9.0%	43.3%	35.8%	10.4%	1.5%		2.5	0.9
Delayed Wound Healing	12	25.0%	50.0%	25.0%	0.0%	0.0%		2.0	0.7
Fluid Accumulation	3	0.0%	33.3%	33.3%	33.3%	0.0%		3.0	1.0
Hematoma	5	20.0%	0.0%	60.0%	0.0%	20.0%		3.0	1.4
Hypertrophic Scarring	23	17.4%	47.8%	21.7%	8.7%	4.3%		2.3	1.0
Implant Extrusion	1	100.0%	0.0%	0.0%	0.0%	0.0%		1.0	N/A**
Implant Malposition	23	13.0%	34.8%	43.5%	4.3%	4.3%		2.5	0.9
Implant Palpability	11	54.5%	18.2%	27.3%	0.0%	0.0%		1.7	0.9
Infection	2	0.0%	100.0%	0.0%	0.0%	0.0%		2.0	0.0
Irritation	2	50.0%	50.0%	0.0%	0.0%	0.0%		1.5	0.7
Loss of Nipple Sensation	18	11.1%	5.6%	55.6%	16.7%	11.1%		3.1	1.1
Loss of Skin Sensation	11	27.3%	18.2%	45.5%	0.0%	9.1%		2.5	1.2
Lymphadenopathy	2	0.0%	50.0%	0.0%	50.0%	0.0%		3.0	1.4
Lymphedema	1	0.0%	0.0%	0.0%	0.0%	100.0%		5.0	N/A**
Nipple Hypersensitivity	9	33.3%	44.4%	11.1%	11.1%	0.0%		2.0	1.0

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Table 157 (Cont.): Worst Case Severity Levels of Complications Through 2 Years

		Severity Level* (Allowable Range 1 - 5)						
	Patients	Very Mild	Mild	Moderate	Severe	Very Severe	Descriptive Statistics	
Complication	N	%	%	%	%	%	Mean	SD
Nipple Paresthesia	3	33.3%	0.0%	33.3%	33.3%	0.0%	2.7	1.5
Other Abnormal Scarring	13	30.8%	38.5%	15.4%	7.7%	7.7%	2.2	1.2
Other Nipple Related Obs.	13	30.8%	15.4%	46.2%	0.0%	7.7%	2.4	1.2
Ptosis	13	15.4%	38.5%	38.5%	7.7%	0.0%	2.4	0.9
Redness	10	10.0%	50.0%	40.0%	0.0%	0.0%	2.3	0.7
Seroma	11	36.4%	36.4%	9.1%	18.2%	0.0%	2.1	1.1
Skin Hypersensitivity	3	66.7%	33.3%	0.0%	0.0%	0.0%	1.3	0.6
Skin Paresthesia	2	0.0%	0.0%	50.0%	0.0%	50.0%	4.0	1.4
Skin Rash	15	20.0%	26.7%	40.0%	13.3%	0.0%	2.5	1.0
Swelling	114	19.3%	51.8%	23.7%	0.0%	5.3%	2.2	0.9
Tissue or Skin Necrosis	1	0.0%	0.0%	0.0%	100.0%	0.0%	4.0	N/A**
Wrinkling/Rippling	8	37.5%	50.0%	0.0%	0.0%	12.5%	2.0	1.3
Other Complications	9	22.2%	44.4%	33.3%	0.0%	0.0%	2.1	0.8

* Severity level ranged from 1 (very mild) to 5 (very severe).
** Standard Deviation (SD) is N/A (Not Applicable) because N = 1.
*** Includes capsular contracture and breast firmness: Baker Grade I-IV for capsular contracture are indicated above as severity levels 1 to 4; severity for firmness ranged from 1 to 5.

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Table 158: Implant Rupture

Implant Rupture	Implants n	Implants %(N = 987)
No Rupture	978	99.1%
Rupture Suspected Through:		
Explant	1	0.1%
MRI	5	0.5%
Reoperation	2	0.2%
Mammography	0	0.0%
Ultrasound	0	0.0%
Physician Exam	1	0.1%
	987	100.0%

Physician Exam – Symptom of Rupture	n	%(N = 1)
Lump/Mass/Nodules	0	0.0%
Implant Distortion	0	0.0%
Burning Sensation	0	0.0%
Softer Breast Texture	0	0.0%
Decreased Breast Size	0	0.0%
Pain/Tenderness	1	100.0%
Motor Vehicle Accident	1	100.0%
	2*	100.0%

* The sum of rupture symptoms listed may exceed the total number of implants identified as ruptured by physician exam because more than one symptom may be reported for the same implant.

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Table 159: Suspected Implant Ruptures

Suspected Implant Ruptures	Implant Ruptures Identified	
	n	%(N = 9)
Confirmed Rupture by Explant	2	22.2%
False Report: Device Intact		
Explant Indicated Non-Rupture	1	11.1%
Mammography* Indicated Non-Rupture	3	33.3%
Ultrasound* Indicated Non-Rupture	1	11.1%
MRI* Indicated Non-Rupture	0	0.0%
Unconfirmed Rupture Status	2	22.2%
	9	100.0%

* Follow-up diagnostic test

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Table 160: Risk of First Occurrence of Implant Rupture

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	0	481	0.0% (0.0%, 0.0%)	0	961	0.0% (0.0%, 0.0%)
6 Months	1	473	0.2% (0.0%, 0.6%)	1	944	0.1% (0.0%, 0.3%)
1 Year	2	461	0.4% (0.0%, 1.0%)	2	920	0.2% (0.0%, 0.5%)
2 Years	4	421	0.9% (0.0%, 1.7%)	4	842	0.4% (0.0%, 0.8%)

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Table 161: Incidence and Prevalence of Implant Rupture

	By Patient			By Implant		
Time	Incidence	Prevalence	Number Evaluated	Incidence	Prevalence	Number Evaluated
4 Weeks	0 (0.0%)	0 (0.0%)	493	0 (0.0%)	0 (0.0%)	985
6 Months	1 (0.2%)	1 (0.2%)	481	1 (0.1%)	1 (0.1%)	961
1 Year	1 (0.2%)	1 (0.2%)	473	1 (0.1%)	1 (0.1%)	944
2 Years	2 (0.4%)	3 (0.6%)	462	2 (0.2%)	3 (0.3%)	921

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Table 162: Distribution of Implant Rupture Resolution Status

Resolution Status	By Patient	
	n	%(N = 4)
Not Yet Resolved		
Undergoing Treatment	2	50.0%
Treatment Not Possible	0	0.0%
Refused Treatment	0	0.0%
Total	2	50.0%
Resolved		
With Reoperation and Explantation	2	50.0%
With Reoperation Without Explantation	0	0.0%
With Non-Surgical Treatment	0	0.0%
Without Treatment	0	0.0%
Total	2	50.0%

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Table 163: Risk of First Occurrence of Reoperation

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	8	474	1.6% (0.5%, 2.8%)	8	955	0.8% (0.3%, 1.4%)
6 Months	28	452	5.8% (3.7%, 7.9%)	38	921	3.9% (2.7%, 5.2%)
1 Year	54	424	11.2% (8.4%,14.1%)	81	873	8.4% (6.7%,10.2%)
2 Years	81	370	17.1% (13.7%,20.5%)	125	773	13.2% (11.1%,15.4%)

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Table 164: Number of Reoperations Per Patient

	Patients (N = 494)	
	n	%
No Reoperations	413	83.6%
At Least One Reoperation	81	16.4%
Total	494	100.0%

Breakdown of At Least One Reoperation	n	%(N = 81)
1 Reoperation	71	87.7%
2 Reoperations	10	12.3%
Total	81	100.0%
Total Number of Reoperations	91*	

* Total number of reoperations is calculated as:
(71 * 1 reoperation) + (10 * 2 reoperations) = 91 reoperations.

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Table 165: Intraoperative Complications During Reoperation

Intraoperative Complications	Reoperations	
	n	%(N = 91)
Yes	0	0.0%
No	88	96.7%
Unknown*	3	3.3%
	91	100.0%

* The implanting study physician did not perform the reoperation for these patients. No information regarding intraoperative complications was able to be obtained from the non-study surgeons who performed these reoperations.

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Table 166: Primary* Reason for Reoperation

Reason	Patient Reoperations n	%(N = 91)
Device Malfunction - Rupture	1	1.1%
Injury - Iatrogenic or Traumatic	0	0.0%
Breast Cancer	0	0.0%
Capsular Contracture	31	34.1%
Infection	0	0.0%
Healing Related		
Extrusion	1	1.1%
Necrosis	1	1.1%
Hematoma/Seroma	5	5.5%
Delayed Wound Healing	1	1.1%
Nipple Complications	1	1.1%
Pain	1	1.1%
Unsatisfactory Cosmetic Result		
Breast Tissue Contour Deformity	0	0.0%
Malposition	15	16.5%
Wrinkling/Rippling	0	0.0%
Implant Palpability/Visibility	0	0.0%
Asymmetry	1	1.1%
Ptosis	12	13.2%
Scarring	9	9.9%
Patient Request		
Style/Size Change	3	3.3%
Media Anxiety	1	1.1%
Need for Biopsy	8	8.8%
Other	0	0.0%
Total	91	100.0%

* Some reoperations were performed for multiple reasons; only the primary reason is provided in the table. In cases where multiple reasons for reoperation were given, the primary reason was determined using a hierarchy as defined by the listed ordering of reasons.

Table 167: Primary* Procedure Performed

Procedure	Patient Reoperations	
	n	%(N = 91)
Implant Removal		
With Replacement**	21	23.1%
Without Replacement	1	1.1%
Capsule Procedure		
Capsulotomy	14	15.4%
Capsulorraphy	3	3.3%
Capsulectomy	8	8.8%
Flap Procedure	0	0.0%
Pocket Revision	3	3.3%
Reposition Implant	3	3.3%
Surgical Exploration of Breast Area or Implant	1	1.1%
Mastopexy	12	13.2%
Breast Reduction	0	0.0%
Wound Repair	2	2.2%
Aspiration of Hematoma/Seroma	5	5.5%
Liposuction	0	0.0%
Removal of Excess Tissue/Lesion/Cyst	0	0.0%
Revision of Nipple Reconstruction/Tattoo	1	1.1%
Scar Revision	9	9.9%
Biopsy	8	8.8%
Other	0	0.0%
Total	91	100.0%

* Some reoperations involved multiple procedures. Only the primary procedure is provided in the table. In cases where multiple procedures were performed, the primary procedure was determined using a hierarchy as defined by the listed ordering of procedures.

** Includes 1 patient who had delayed replacement. This patient had a device removal without replacement in 3/99, and then had a new device placed in 9/99.

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Table 168: Primary* Reason For Reoperation and Primary Procedure Performed

Reason	Procedure	Patient Reoperations n	Patient Reoperations %(N = 91)
Device Rupture	Implant Replacement/Removal	1	1.1%
Capsular Contracture	Implant Replacement/Removal	12	13.2%
	Capsule Procedure	19	20.9%
Healing Related	Implant Replacement/Removal	1	1.1%
	Revision of Nipple Reconstruction/Tattoo	1	1.1%
	Aspiration of Hematoma/Seroma	5	5.5%
	Wound Repair	2	2.2%
Pain	Capsule Procedure	1	1.1%
Unsatisfactory Cosmetic Result	Implant Replacement/Removal	4	4.4%
	Capsule Procedure	5	5.5%
	Scar Revision	9	9.9%
	Mastopexy	12	13.2%
	Reposition Implant	3	3.3%
	Pocket Revision	3	3.3%
	Surgical Exploration of Breast Area or Implant	1	1.1%
Patient Request	Implant Replacement/Removal	4	4.4%
Need for Biopsy	Biopsy	8	8.8%
Total		91	100.0%

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Table 168 (cont.): Primary* Reason For Reoperation and Primary Procedure Performed

* Some reoperations involved multiple reasons for reoperation and/or multiple procedures performed. Only the primary reason/procedure is provided in the table. In cases where multiple reasons/procedures were given, the primary reason/procedure was determined using a hierarchy.

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Table 169: Number of Procedures Performed Per Reoperation

Number of Procedures	Reoperations	
	n	%(N = 91)
1	38	41.8%
2	31	34.1%
3	3	3.3%
4	13	14.3%
5	2	2.2%
6	4	4.4%
Total	91	100.0%
Total Number of Procedures	195*	

* Total number of procedures is calculated as:
(38 * 1 procedure) + (31 * 2 procedures) + (3 * 3 procedures)
+ (13 * 4 procedures) + (2 * 5 procedures)
+ (4 * 6 procedures) = 195 procedures.

Table 170: Type of Procedure Performed During Reoperation

Type of Procedure	Procedures n	Procedures %(N = 195)
Implant Removal		
With Replacement	39	20.0%
Without Replacement	2	1.0%
Capsule Procedure		
Capsulotomy	39	20.0%
Capsulorraphy	4	2.1%
Capsulectomy	24	12.3%
Flap Procedure	0	0.0%
Pocket Revision	5	2.6%
Reposition Implant	11	5.6%
Surgical Exploration of Breast Area or Implant	2	1.0%
Mastopexy	32	16.4%
Breast Reduction	0	0.0%
Wound Repair	2	1.0%
Aspiration of Hematoma/Seroma	5	2.6%
Liposuction	0	0.0%
Removal of Excess Tissue/Lesion/Cyst	1	0.5%
Revision of Nipple Reconstruction/Tattoo	2	1.0%
Scar Revision	18	9.2%
Biopsy	9	4.6%
Other	0	0.0%
Total	195	100.0%

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Table 171: Risk of First Occurrence of Implant Replacement/Removal

	By Patient				By Implant			
	Number Affected	Number Remaining	Cumulative Risk		Number Affected	Number Remaining	Cumulative Risk	
Time	n	n	%	(95% CI)	n	n	%	(95% CI)
4 Weeks	0	481	0.0%	--	0	961	0.0%	--
6 Months	4	475	0.8%	(0.0%, 1.6%)	7	950	0.7%	(0.2%, 1.3%)
1 Year	13	462	2.7%	(1.3%, 4.2%)	24	925	2.5%	(1.5%, 3.5%)
2 Years	22	421	4.7%	(2.8%, 6.6%)	41	844	4.4%	(3.1%, 5.7%)

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Table 172: Risk of First Occurrence of Implant Removal With Replacement

	By Patient				By Implant			
	Number Affected	Number Remaining		Cumulative Risk	Number Affected	Number Remaining		Cumulative Risk
Time	n	n	%	(95% CI)	n	n	%	(95% CI)
4 Weeks	0	481	0.0%	--	0	961	0.0%	--
6 Months	4	475	0.8%	(0.0%, 1.6%)	7	950	0.7%	(0.2%, 1.3%)
1 Year	13	462	2.7%	(1.3%, 4.2%)	24	925	2.5%	(1.5%, 3.5%)
2 Years	21	421	4.5%	(2.6%, 6.4%)	39	844	4.2%	(2.9%, 5.4%)

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Table 173: Risk of First Occurrence of Implant Removal Without Replacement

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	0	481	0.0% --	0	961	0.0% --
6 Months	0	473	0.0% (0.0%, 0.0%)	0	944	0.0% (0.0%, 0.0%)
1 Year	0	462	0.0% (0.0%, 0.0%)	0	921	0.0% (0.0%, 0.0%)
2 Years	1	424	0.2% (0.0%, 0.7%)	2	844	0.2% (0.0%, 0.5%)

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Table 174: Primary* Reason for Implant Replacement/Removal

Reason	Implant Removals	
	n	%(N = 41)
Device Malfunction - Rupture	2	4.9%
Injury - Iatrogenic or Traumatic	0	0.0%
Breast Cancer	0	0.0%
Capsular Contracture	19	46.3%
Infection	0	0.0%
Healing Related		
Extrusion	1	2.4%
Necrosis	0	0.0%
Hematoma/Seroma	0	0.0%
Delayed Wound Healing	0	0.0%
Nipple Complications	0	0.0%
Pain	0	0.0%
Unsatisfactory Cosmetic Result		
Breast Tissue Contour Deformity	0	0.0%
Malposition	6	14.6%
Wrinkling	0	0.0%
Implant Palpability/Visibility	0	0.0%
Asymmetry	3	7.3%
Ptosis	0	0.0%
Unsatisfactory Scar	0	0.0%
Patient Request		
Style/Size Change	7	17.1%
Media Anxiety	3	7.3%
Biopsy	0	0.0%
Other	0	0.0%
Total	41	100.0%

* Some implant replacements/removals were performed for multiple reasons. Only the primary reason is provided in the table. In cases where multiple reasons were given, the primary reason was determined using a hierarchy as defined by the listed ordering of reasons.

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Table 175: Physician Evaluation of Explanted Devices

Characteristic	Ruptured Implants (n = 2)		Intact (Non-Ruptured) Implants (n = 39)	
	Yes(%)	No(%)	Yes(%)	No(%)
Capsule Torn*	0 (0.0%)	2(100.0%)	0 (0.0%)	39 (100.0%)
Extracapsular Gel	0 (0.0%)	2(100.0%)	0 (0.0%)	39 (100.0%)
Gel on Implant Surface	2 (100.0%)	0 (0.0%)	0 (0.0%)	39 (100.0%)
Removal Difficult	0 (0.0%)	2(100.0%)	2 (5.1%)	37 (94.9%)

* Capsule not intact

Table 176: Distribution of Type of Replacement Implant

Type of Replacement Implant	By Implant	
	n	%(N = 39)
McGhan Medical Study Device	33	84.6%
Non-McGhan Medical Device	4	10.3%
Unknown Device Type*	2	5.1%
Total	39	100.0%

* The implanting study physician did not perform the implant replacement/removal procedure for these patients. No information regarding type of replacement implant was able to be obtained from the non-study surgeons who performed these implant replacement/removal procedures.

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Table 177: McGhan Replacement Implant Size vs. Primary Implant

Size Change	By Implant	
	n	%(N = 33)
Increase in Size	25	75.8%
No Change in Size	6	18.2%
Decrease in Size	2	6.1%
Total	33	100.0%

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Table 178: Risk of First Occurrence of Any General Breast Surgery Complication

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	56	427	11.4% (8.6%,14.3%)	90	875	9.2% (7.4%,11.0%)
6 Months	71	407	14.6% (11.4%,17.7%)	113	842	11.6% (9.6%,13.6%)
1 Year	82	388	16.9% (13.6%,20.2%)	130	806	13.4% (11.2%,15.5%)
2 Years	95	345	19.8% (16.2%,23.4%)	150	725	15.6% (13.3%,17.9%)

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Table 179: Risk of First Occurrence of Any Breast Implant Surgery - Cosmetic Complication

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	9	472	1.8% (0.7%, 3.0%)	11	950	1.1% (0.5%, 1.8%)
6 Months	17	458	3.5% (1.9%, 5.2%)	25	923	2.6% (1.6%, 3.6%)
1 Year	24	443	5.0% (3.1%, 7.0%)	37	894	3.9% (2.6%, 5.1%)
2 Years	33	404	7.0% (4.7%, 9.3%)	52	814	5.6% (4.1%, 7.0%)

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Table 180: Risk of First Occurrence of Any Breast Implant Surgery - Non-Cosmetic Complication

	By Patient			By Implant		
	Number Affected	Number Remaining	Cumulative Risk	Number Affected	Number Remaining	Cumulative Risk
Time	n	n	% (95% CI)	n	n	% (95% CI)
4 Weeks	2	479	0.4% (0.0%, 1.0%)	4	957	0.4% (0.0%, 0.8%)
6 Months	11	467	2.3% (1.0%, 3.6%)	17	937	1.8% (0.9%, 2.6%)
1 Year	25	448	5.2% (3.2%, 7.2%)	41	901	4.3% (3.0%, 5.6%)
2 Years	36	404	7.7% (5.3%,10.1%)	55	820	5.9% (4.4%, 7.4%)

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Table 181: Pre-Implant Reproduction Problems

	Patients	
Reproduction Problems	n	%(N = 494)
No Reproduction Problem	413	83.6%
Reproduction Problem	81	16.4%
	494	100.0%

Type Of Reproduction Problem	n	%(N = 81)
Infertility	20	24.7%
Spontaneous Abortion (Miscarriage)	51	63.0%
Planned Abortion to Treat a Medical Problem	9	11.1%
Ectopic Pregnancy	9	11.1%
Stillbirth	0	0.0%
Other	5	6.2%
	94*	116.0%

* The sum of reproduction problems listed may exceed the total number of patients with reproduction problems because a patient may have had more than one reproduction problem.

Table 181 (cont.): Pre-Implant Reproduction Problems

Other Reproduction Problem Specified (N = 5)

Pt Seq#	Other Reproduction Problem Specified
001	CERVICAL LIGATION PLACENTIA PREVIA
002	HSYTERECTOMY DONE FOR UNKNOWN REASONS
003	HYSTERECTOMY DONE FOR UNKNOWN REASONS
004	ENDOMETRIOSIS
005	HYSTERECTOMY DONE FOR UNKNOWN REASONS

Table 182: Post-Implant Reproduction Problems Through 2 Years

	Patients	
Reproduction Problems	n	%(N = 494)
No Reproduction Problem	489	99.0%
Reproduction Problem	5	1.0%
	494	100.0%

Type Of Reproduction Problem	n	%(N = 5)
Infertility	0	0.0%
Spontaneous Abortion (Miscarriage)	4	80.0%
Planned Abortion to Treat a Medical Problem	0	0.0%
Ectopic Pregnancy	0	0.0%
Stillbirth	0	0.0%
Other	1	20.0%
	5	100.0%

Table 182 (cont.): Post-Implant Reproduction Problems Through 2 Years

Other Reproduction Problem Specified (N = 1)

Pt Seq#	Other Reproduction Problem Specified
001	ENDOMETRIOSIS

Table 183: Pre-Implant Lactation Problems

Lactation Problems	Patients n	Patients %(N = 494)
No Lactation Problem	452	91.5%
Lactation Problem	42	8.5%
	494	100.0%

Type Of Lactation Problem	n	%(N = 42)
Mastitis Not Requiring Treatment	6	14.3%
Mastitis Requiring Treatment	16	38.1%
Inadequate Milk Production	19	45.2%
Excess Milk Production	4	9.5%
Pain	5	11.9%
Other	2	4.8%
	52*	123.8%

* The sum of lactation problems listed may exceed the total number of patients with lactation problems because a patient may have had more than one lactation problem.

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Table 183 (cont.): Pre-Implant Lactation Problems

Other Lactation Problem Specified (N = 2)

Pt Seq#	Other Lactation Problem Specified
001	CHOLIC
002	CLOGGED MILK DUCT

Table 184: Post-Implant Lactation Problems Through 2 Years

	Patients	
Lactation Problems	n	%(N = 494)
No Lactation Problem	490	99.2%
Lactation Problem	4	0.8%
	494	100.0%

Type Of Lactation Problem	n	%(N = 4)
Mastitis Not Requring Treatment	1	25.0%
Mastitis Requring Treatment	2	50.0%
Inadequate Milk Production	2	50.0%
Excess Milk Production	1	25.0%
Pain	1	25.0%
Other	1	25.0%
	8*	200.0%

* The sum of lactation problems listed may exceed the total number of patients with lactation problems because a patient may have had more than one lactation problem.

Table 184 (cont.): Post-Implant Lactation Problems Through 2 Years

Other Lactation Problem Specified (N = 1)

Pt Seq#	Other Lactation Problem Specified
001	DECREASE VOLUME MILK (STILL ADEQUATE)

Table 185: Pre-Implant Breast Disease

Breast Disease	Patients n	Patients %(N = 494)
No Breast Disease	464	93.9%
Breast Disease	30	6.1%
	494	100.0%

Type Of Breast Disease	n	%(N = 30)
Benign Disease	29	96.7%
Unknown Breast Disease*	1	3.3%
	30	100.0%

* This patient's pre-operative mammogram indicated a cyst, most likely benign. The patient's physician recommended a follow-up mammogram in 6 months to confirm the benign finding; this patient did not obtain a follow-up mammogram.

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Table 186: Post-Implant Breast Disease Through 2 Years

	Patients	
Breast Disease	n	%(N = 494)
No Breast Disease	467	94.5%
Breast Disease	27	5.5%
	494	100.0%

Type Of Breast Disease	n	%(N = 27)
Confirmed Malignant Disease	1	3.7%
Benign Disease	25	92.6%
Unknown Breast Disease*	1	3.7%
	27	100.0%

* This patient had a breast lump noted during her 1 year follow-up exam and was referred for a mammogram; the patient has not yet had the recommended diagnostic mammogram.

Table 187: Pre-Implant Mammogram Result

Mammogram Results	Patients n	Patients %(N = 494)
No Pre-Implant Mammogram	309	62.6%
Pre-Implant Mammogram		
Normal Mammogram	180	36.4%
Abnormal Mammogram	5	1.0%
	494	100.0%

Disposition Of Patients With Abnormal Mammogram Results	n	%(N = 5)
Benign Disease	4	80.0%
Unknown Breast Disease*	1	20.0%
	5	100.0%

* This patient's pre-operative mammogram indicated a cyst, most likely benign. The patient's physician recommended a follow-up mammogram in 6 months to confirm the benign finding; this patient did not obtain a follow-up mammogram.

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Table 188: Post-Implant Mammogram Result Through 2 Years

Mammogram Results	Patients n	Patients %(N = 494)
No Post-Implant Mammogram	358	72.5%
Post-Implant Mammogram		
Normal Mammogram	128	25.9%
At Least One Abnormal Mammogram	8	1.6%
	494	100.0%

Disposition Of Patients With Abnormal Mammogram Results	n	%(N = 8)
No Breast Disease	1	12.5%
Benign Disease	7	87.5%
	8	100.0%

Table 189: Pre-Implant Connective Tissue/Autoimmune Disease (CTD)

CTD	Patients	
	n	%(N = 494)
No CTD	494	100.0%
CTD		
Confirmed CTD	0	0.0%
Unconfirmed CTD	0	0.0%
Total	494	100.0%

Table 190: Post-Implant Connective Tissue/Autoimmune Disease (CTD) Through 2 Years

CTD	Patients n	Patients %(N = 494)
No CTD	493	99.8%
CTD		
Confirmed CTD	1	0.2%
Unconfirmed CTD	0	0.0%
	494	100.0%

Confirmed CTD Specified (N = 1)

Pt Seq#	CTD Specified	# of Months Between Implant Surgery and Onset
001	Rheumatoid Arthritis	11

Table 191: Change in Pre- vs. Post-Implant* Bra Cup Size

Size Change	Patients	
	n	%(N = 408)
-2 Cups	1	0.3%
-1 Cup	1	0.3%
No Change	22	5.4%
+1 Cup	165	40.4%
+2 Cups	185	45.3%
+3 Cups	33	8.1%
+4 Cups	1	0.3%
Total	408	100.0%

* Post-implant bra size is the first valid bra size (inches and cup) reported between one month and 18 months after implant surgery. If the patient had a post-implant pregnancy that occurred on or before the time her first valid post-implant bra size was reported, then her data is excluded.

Table 192: Comparison of Pre- vs. Post-Implant Bra Cup Size

	Pre- vs Post-Implant* Bra Cup Size (N = 408)							
Post-Implant* Cup Size	Pre-Implant Cup Size AA	A	B	C	D	DD	E	F
Frequency								
AA	0	0	0	0	0	0	0	0
A	0	0	0	0	0	0	0	0
B	5	36	8	1	0	0	0	0
C	9	133	107	11	0	0	0	0
D	1	22	40	21	2	0	1	0
DD	0	0	2	7	1	1	0	0
E	0	0	0	0	0	0	0	0
F	0	0	0	0	0	0	0	0
	15	191	157	40	3	1	1	0
Percent								
AA	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
A	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
B	33.3%	18.8%	5.1%	2.5%	0.0%	0.0%	0.0%	0.0%
C	60.0%	69.6%	68.2%	27.5%	0.0%	0.0%	0.0%	0.0%
D	6.7%	11.5%	25.5%	52.5%	66.7%	0.0%	100.0%	0.0%
DD	0.0%	0.0%	1.3%	17.5%	33.3%	100.0%	0.0%	0.0%
E	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
F	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	0.0%

* Post-implant bra size is the first valid bra size (inches and cup) reported between one month and 18 months after implant surgery. If the patient had a post-implant pregnancy that occurred on or before the time her first valid post-implant bra size was reported, then her data is excluded.

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Table 193: Pre- vs. Post-Implant Bra Size

	Bra Size Numerical Scale* (Allowable Range 1 - 13)						
	Descriptive Statistics			Paired t-test Results			
Time	Mean	SD	Range	N	df	t	p
Pre-Implant	4.7	1.2	2 - 9	408	407	40.63	<0.001
Post-Implant**	6.6	1.0	4 - 10				

* Each valid bra size (inches and cup) was translated into a numerical scale score from 1 to 13, with each one-step increase in bra inches (e.g., 34 to 36) or cup size (e.g., B to C) resulting in a one-score increase on the scale. For example, the lowest scale score (1) was assigned to the smallest possible bra size "30AA". A "32AA" was assigned a scale score of 2, as was a "30A"; a "32A" was assigned a scale score of 3, and so forth.

**Post-implant bra size is the first valid bra size (inches and cup) reported between one month and 18 months after implant surgery. If the patient had a post-implant pregnancy that occurred on or before the time her first valid post-implant bra size was reported, then her data is excluded.

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Table 194: Pre- vs. Post-Implant Lateral Breast Measurement, By Breast

	Lateral Breast Measurement (cm) (Allowable Range 1 - 60cm)						
	Descriptive Statistics			Paired t-test Results			
Time	Mean	SD	Range	N	df	t	p
Pre-Implant	17.4	3.8	11.0-38.0	745	744	40.59	<0.001
Post-Implant*	22.1	3.8	11.0-36.0				

* Post-implant lateral breast measurement is the first lateral breast measurement reported between one month and 18 months after implant surgery. If the patient had a post-implant pregnancy that occurred on or before the time her first post-implant lateral breast measurement was reported, then her data is excluded.

CORE STUDY - AUGMENTATION

Table 195: Physician Assessment of Implants

		Satisfaction Level* (Allowable Range 1 - 5)							
	Patients	Definitely Dissat-isfied		Somewhat Dissat-isfied		Somewhat Satisfied		Definitely Satisfied		Descriptive Statistics	
Time	N	%		%		%		%		Mean	SD
0-4 Weeks	488	0.0%		0.2%		0.2%		4.7%	94.9%	4.9	0.3
6 Months	409	0.7%		2.0%		0.5%		6.6%	90.2%	4.8	0.6
1 Year	412	0.0%		1.9%		0.5%		6.6%	91.0%	4.9	0.5
2 Years	424	0.5%		2.1%		0.7%		7.8%	88.9%	4.8	0.6

* Satisfaction level could range from 1 (definitely dissatisfied) to 5 (definitely satisfied).

CORE STUDY - AUGMENTATION

Table 196: Physician Dissatisfaction with Implants

	Physician Dissatisfaction Specified					
	Patients			Implants		
Time	n	Yes(%)*	No(%)	n	Yes(%)*	No(%)
0-4 Weeks	488	1 (0.2%)	487 (99.8%)	975	2 (0.2%)	973 (99.8%)
6 Months	409	13 (3.2%)	396 (96.8%)	815	18 (2.2%)	797 (97.8%)
1 Year	412	9 (2.2%)	403 (97.8%)	821	11 (1.3%)	810 (98.7%)
2 Years	424	19 (4.5%)	405 (95.5%)	844	29 (3.4%)	815 (96.6%)

* Includes all patients/implants for which a specific dissatisfaction was indicated, regardless of the satisfaction rating (1-5) provided.

CORE STUDY - AUGMENTATION

Table 197: Type of Physician Dissatisfaction with Implants

		Type of Dissatisfaction Specified			
			Implant	Medical/	
	Implants	Aesthetic	Design	Procedural	Other
Time	N	%	%	%	%
0-4 Weeks	2	50.0%	0.0%	50.0%	0.0%
6 Months*	18	33.3%	0.0%	77.8%	0.0%
1 Year	11	27.3%	0.0%	72.7%	0.0%
2 Years	29	17.2%	0.0%	82.8%	0.0%

* The sum of the percentages across types of dissatisfaction may exceed 100% because a physician may have specified more than one type of dissatisfaction for an implant.

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Table 198: Patient Assessment of Implants

		Satisfaction Level* (Allowable Range 1 - 5)						
	Patients	Definitely Dissat-isfied	Somewhat Dissat-isfied	Somewhat Satisfied	Satisfied	Definitely Satisfied	Descriptive Statistics	
Time	N	%	%	%	%	%	Mean	SD
0-4 Weeks	488	0.2%	0.2%	0.2%	6.4%	93.0%	4.9	0.3
6 Months	409	1.0%	1.5%	0.5%	9.8%	87.3%	4.8	0.6
1 Year	412	0.7%	2.7%	0.5%	12.6%	83.5%	4.8	0.7
2 Years	425	0.9%	3.1%	1.2%	9.4%	85.4%	4.8	0.7

* Satisfaction level could range from 1 (definitely dissatisfied) to 5 (definitely satisfied).

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Table 199: Patient Dissatisfaction with Implants

Patient Dissatisfaction Specified

Time	Patients			Implants		
	n	Yes(%)*	No(%)	n	Yes(%)*	No(%)
0-4 Weeks	488	2 (0.4%)	486 (99.6%)	975	4 (0.4%)	971 (99.6%)
6 Months	409	12 (2.9%)	397 (97.1%)	815	17 (2.1%)	798 (97.9%)
1 Year	412	19 (4.6%)	393 (95.4%)	821	27 (3.3%)	794 (96.7%)
2 Years	425	24 (5.6%)	401 (94.4%)	846	34 (4.0%)	812 (96.0%)

* Includes all patients/implants for which a specific dissatisfaction was indicated, regardless of the satisfaction rating (1-5) provided.

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Table 200: Type of Patient Dissatisfaction with Implants

		Type of Dissatisfaction Specified			
	Implants	Aesthetic	Implant Design	Medical/ Procedural	Other
Time	N	%	%	%	%
0-4 Weeks	4	100.0%	0.0%	0.0%	0.0%
6 Months*	17	52.9%	0.0%	58.8%	0.0%
1 Year	27	40.7%	0.0%	59.3%	0.0%
2 Years	34	23.5%	0.0%	76.5%	0.0%

* The sum of the percentages across types of dissatisfaction may exceed 100% because a patient may have specified more than one type of dissatisfaction for an implant.

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Table 201: Patient Assessment of Implants, with Both Primary and Secondary Study Devices Included

		Satisfaction Level* (Allowable Range 1 - 5)							
	Patients	Definitely Dissat-isfied	Somewhat Dissat-isfied	Somewhat Satisfied	Satisfied	Definitely Satisfied	Descriptive Statistics		
Time	N	%	%	%	%	%	Mean	SD	
0-4 Weeks	488	0.2%	0.2%	0.2%	6.4%	93.0%	4.9	0.3	
6 Months	412	1.0%	1.5%	0.5%	9.7%	87.4%	4.8	0.6	
1 Year	421	0.7%	2.9%	0.5%	13.5%	82.4%	4.7	0.7	
2 Years	439	1.1%	3.0%	1.1%	9.8%	85.0%	4.7	0.7	

* Satisfaction level could range from 1 (definitely dissatisfied) to 5 (definitely satisfied).

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Table 202: Motivations for Having Breast Implant Surgery

Reason	Patients	Level of Importance* (Allowable Range 1 - 5) Not At All	A Little Bit	Moderately	Quite A Bit	Extremely
	N	%	%	%	%	%
To Please My Partner	481	32.6%	24.9%	23.9%	12.3%	6.2%
To Improve My Sex Life	482	40.0%	23.7%	22.0%	11.2%	3.1%
To Make Me Feel Better About My Physical Appearance	484	0.6%	2.9%	9.1%	35.1%	52.3%
To Improve the Way I Feel About Myself	485	9.5%	12.6%	19.4%	28.0%	30.5%
To Increase My Chance of Meeting A Partner	477	87.2%	6.3%	5.2%	0.6%	0.6%
Other Reason	49	2.0%	6.1%	6.1%	26.5%	59.2%

* Level of importance could range from 1 (not at all important) to 5 (extremely important).

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Table 202 (cont.) : Motivations for Having Breast Implant Surgery

Other Reason Specified (N = 49)

Pt Seq#	Other Reason Specified
001	CLOTHING WILL FIT BETTER
002	FEEL MORE FEMININE
003	TO GO BACK TO MY NORMAL SIZE BEFORE CHILDBIRTH
004	REGAIN PRE-CHILDREN FORM
005	Other Reason not Specified
006	SELF CONFIDENCE
007	Other Reason not Specified
008	LIFT/FULL(NURSED 3 KIDS)
009	IMPROVE BREASTS AFTER EXPERIENCING LESS BREAST TISSUE AFTER HAVING CHILDREN
010	UPGRADE SELFESTEEM
011	BE ABLE TO BUY A BRA THAT FITS
012	GETTING MARRIED
013	TO FIT INTO A BRA!
014	ITS AVAILABLE
015	BECAUSE PEOPLE ARE RESPONSIVE TO LOOKS
016	TO HOLD UP A STRAPLESS DRESS.
017	NO MORE PADDED BRA
018	LIFETIME MAINTENANCE
019	TO LOOK PORPORTIONATE

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Table 202 (cont.) : Motivations for Having Breast Implant Surgery

Other Reason Specified (N = 49)

Pt Seq#	Other Reason Specified
020	X-MAS PRESENT FOR MYSELF WANTED SINCE I WAS 18 YRS OLD
021	TO LOOK BETTER WITH OR W/OUT CLOTHES
022	REGAIN PRE PREGNANCY SIZE
023	RESTORE THEM TO PRE CHILDBEARING
024	FIND A BRA THAT FITS
025	SO I CAN WEAR OTHER FASHIONS THAT LOOK GOOD W/MORE BUST-LINE
026	LOOK MORE ATTRACTIVE
027	TO BEABLE TO WEAR REVEALING CLOTHES
028	FIT INTO CLOTHES BETTER
029	IVE SHRUNK
030	TO BE WHAT I BELIEVE IS ME
031	CLOTHES FIT BETTER
032	FILL GAP BETWEEN BREAST & PEC
033	TO BALANCE OUT MY BODY
034	IMPROVE APPEARANCE IN CLOTHING
035	AS LONG AS CORRECTING ASYMMETRY ON RT.GETTING WHAT I WANT
036	I ALWAYS FELT I WAS SUPPOSED TO BE BIGGER
037	SO MY CLOTHES FIT BETTER
038	TO BE ABLE TO WEAR THINGS I USED TO

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Table 202 (cont.) : Motivations for Having Breast Implant Surgery

Other Reason Specified (N = 49)

Pt Seq#	Other Reason Specified
039	WORK RELATED
040	TO LOOK MORE PLEASING IN CERTAIR CLOTHES
041	TO FILL OUT CLOTHES
042	IMPROVE BREAST ATROPHY
043	MAKE CLOTHES FIT BETTER
044	PHYSICALLY UNCOMFORTABLE
045	EXERCISE,RUN
046	TO WORK&APPEAR TO BE SEXUALLY COMPETATIVE
047	REPLACE WHAT I HAD BEFORE CHILDREN
048	STOP WORRING ABOUT IT
049	TO FIT A BRA PROPERLY

CORE STUDY - AUGMENTATION

Table 203: Comparison of Patient Pre-Operative Expectation vs. Post-Implant Satisfaction With Breast Implants

Satisfaction with Breast Implants
(Allowable Range 1-5)

	Descriptive Statistics			ANOVA Results			
Time	Mean	S.D.	Range	N	F	df	p
Pre-Operative Expectation*	4.9B	0.4	3.0 - 5.0	351	30.04	2	<0.001
1 Year	4.6A	0.6	1.0 - 5.0				
2 Years	4.6A	0.7	1.0 - 5.0				

* Pre-Operative Expectation is assessed at baseline to measure how much a patient expects to be satisfied with her implants after implantation.

Score: 1 = Very Dissatisfied
2 = Dissatisfied
3 = Neither Satisfied nor Dissatisfied
4 = Satisfied
5 = Very Satisfied

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.05 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different letters.

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Table 204: Patient Satisfaction Rating: Pre-Operative Expectation
vs. Post-Implant Satisfaction with Breast Implants

	%(N = 351 Patients)		
		Post-Op	
Rating	Pre-Op	1 Year	2 Years
Very Dissatisfied	0.0%	0.6%	0.6%
Dissatisfied	0.0%	1.1%	2.0%
Neither Satisfied nor Dissatisfied	0.6%	0.9%	2.6%
Satisfied	13.7%	28.8%	29.3%
Very Satisfied	85.8%	68.7%	65.5%
	100.0%	100.0%	100.0%

CORE STUDY - AUGMENTATION

Table 205: Rowland Expectation Summary

Scale	Table	Mean Score: Pre-Op	Post-Op: 1 Year	Post-Op: 2 Years	p	Effect Size
Improve Self Image	206	3.0A	3.4B	3.4B	*	0.43
Improve Social Relations	207	1.2A	1.5B	1.6B	*	0.59
Improve Daily Living	208	2.6A	2.9B	2.8B	*	0.39
Improve Well-Being	209	N/A	N/A	N/A	--	--

* = p < .001

Significantly different means are indicated with different letters.

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Table 206: Rowland Expectation: Improve Self Image

Rowland Expectation: Improve Self Image
(Allowable Range 1-5)

	Descriptive Statistics			ANOVA Results			
Time	Mean	S.D.	Range	N	F	df	p
Baseline	3.0A	0.8	1.2 - 5.0	352	35.57	2	<0.001
1 Year	3.4B	0.9	1.0 - 5.0				
2 Years	3.4B	1.0	1.0 - 5.0				

Score: 1 = Not At All
2 = Slightly
3 = Moderately
4 = Considerably
5 = Absolutely 100%

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0167 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different letters.

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Table 207: Rowland Expectation: Improve Social Relations

Rowland Expectation: Improve Social Relations
(Allowable Range 1-5)

	Descriptive Statistics			ANOVA Results			
Time	Mean	S.D.	Range	N	F	df	p
Baseline	1.2A	0.4	1.0 - 3.7	352	40.39	2	<0.001
1 Year	1.5B	0.7	1.0 - 4.7				
2 Years	1.6B	0.9	1.0 - 5.0				

Score: 1 = Not At All
2 = Slightly
3 = Moderately
4 = Considerably
5 = Absolutely 100%

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0167 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different letters.

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Table 208: Rowland Expectation: Improve Daily Living

Rowland Expectation: Improve Daily Living
(Allowable Range 1-5)

	Descriptive Statistics			ANOVA Results			
Time	Mean	S.D.	Range	N	F	df	p
Baseline	2.6A	1.0	1.0 - 5.0	350	28.74	2	<0.001
1 Year	2.9B	1.1	1.0 - 5.0				
2 Years	2.8B	1.1	1.0 - 5.0				

Score: 1 = Not At All
2 = Slightly
3 = Moderately
4 = Considerably
5 = Absolutely 100%

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0167 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different letters.

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Table 209: Rowland Expectation: Improve Well-Being

N/A: ROWLAND EXPECTATION: IMPROVE WELL-BEING WAS NOT ASSESSED FOR AUGMENTATION PATIENTS

CORE STUDY - AUGMENTATION

Table 210: Comparison of Baseline SF-36 Scores to General Population

	Mean Score				
	Augmentation Patients	General Population	t	df	p
Role Limitations due to Emotional Problems	95.66	79.47	12.60	1132	<0.001
Role Limitations due to Physical Problems	96.67	77.77	15.34	1421	<0.001
General Health	90.88	70.61	25.52	1160	<0.001
Bodily Pain	91.49	73.59	18.74	1009	<0.001
Social Functioning	97.38	81.54	20.58	1581	<0.001
Physical Functioning	98.08	81.47	21.93	1725	<0.001
Vitality	75.62	58.43	18.33	804	<0.001
Mental Health	84.47	73.25	15.10	980	<0.001
Reported Health Transition	36.35	N/A	N/A	N/A	N/A

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Table 211: SF-36 Summary

Scale	Table	Mean Score					
			Post-Op				Effect
		Pre-Op	1 Year	2 Years	p		Size
Role Limitations due to Emotional Problems	212	95.7B	90.8A	91.3A	**		0.29
Role Limitations due to Physical Health Problems	213	96.7B	94.4B	89.9A	**		0.16
General Health	214	90.9C	88.3B	86.5A	**		0.25
Bodily Pain	215	91.5	91.8	90.4	n.s.		--
Social Functioning	216	97.4B	94.8A	93.7A	**		0.31
Physical Functioning	217	98.1	97.6	96.9	n.s.		--
Vitality	218	75.6B	70.5A	70.1A	**		0.37
Mental Health	219	84.5B	82.6A	81.8A	**		0.18
Reported Health Transition	220	36.3A	43.0B	45.0B	**		0.32

** = p < .001
n.s. = not significant
Significantly different means are indicated with different letters.

CORE STUDY - AUGMENTATION

Table 212: SF-36: Role Limitations Due to Emotional Problems

SF-36: Role Limitations Due to Emotional Problems
(Allowable Range 0-100)

	Descriptive Statistics			ANOVA Results			
Time	Mean	S.D.	Range	N	F	df	p
Baseline	95.7B	16.8	0.0 - 100.0	346	8.21	2	<0.001
1 Year	90.8A	23.3	0.0 - 100.0				
2 Years	91.3A	24.5	0.0 - 100.0				

Score: 100 indicates best possible quality of life

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0056 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different letters.

CORE STUDY - AUGMENTATION

Table 213: SF-36: Role Limitations Due to Physical Health Problems

SF-36: Role Limitations Due to Physical Health Problems
(Allowable Range 0-100)

	Descriptive Statistics			ANOVA Results			
Time	Mean	S.D.	Range	N	F	df	p
Baseline	96.7B	14.3	0.0 - 100.0	345	14.17	2	<0.001
1 Year	94.4B	19.4	0.0 - 100.0				
2 Years	89.9A	25.8	0.0 - 100.0				

Score: 100 indicates best possible quality of life

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0056 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different letters.

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Table 214: SF-36: General Health

SF-36: General Health
(Allowable Range 0-100)

	Descriptive Statistics			ANOVA Results			
Time	Mean	S.D.	Range	N	F	df	p
Baseline	90.9C	10.3	55.0 - 100.0	346	19.70	2	<0.001
1 Year	88.3B	13.4	30.0 - 100.0				
2 Years	86.5A	15.5	15.0 - 100.0				

Score: 100 indicates best possible quality of life

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0056 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different letters.

CORE STUDY - AUGMENTATION

Table 215: SF-36: Bodily Pain

SF-36: Bodily Pain
(Allowable Range 0-100)

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
Baseline	91.5	13.2	22.5 - 100.0	351	1.25	2	0.287
1 Year	91.8	14.1	22.5 - 100.0				
2 Years	90.4	15.6	22.5 - 100.0				

Score: 100 indicates best possible quality of life

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0056 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

CORE STUDY - AUGMENTATION

Table 216: SF-36: Social Functioning

SF-36: Social Functioning
(Allowable Range 1-100)

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
Baseline	97.4B	8.1	50.0 - 100.0	343	12.46	2	<0.001
1 Year	94.8A	12.3	25.0 - 100.0				
2 Years	93.7A	14.4	0.0 - 100.0				

Score: 100 indicates best possible quality of life

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0056 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different letters.

CORE STUDY - AUGMENTATION

Table 217: SF-36: Physical Functioning

SF-36: Physical Functioning
(Allowable Range 0-100)

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
Baseline	98.1	7.1	27.8 - 100.0	348	2.44	2	0.088
1 Year	97.6	9.9	5.0 - 100.0				
2 Years	96.9	9.5	33.3 - 100.0				

Score: 100 indicates best possible quality of life

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0056 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

CORE STUDY - AUGMENTATION

Table 218: SF-36: Vitality

SF-36: Vitality
(Allowable Range 0-100)

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
Baseline	75.6B	13.8	10.0 - 100.0	346	23.01	2	<0.001
1 Year	70.5A	17.8	0.0 - 100.0				
2 Years	70.1A	17.9	10.0 - 100.0				

Score: 100 indicates best possible quality of life

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0056 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different letters.

CORE STUDY - AUGMENTATION

Table 219: SF-36: Mental Health

SF-36: Mental Health
(Allowable Range 0-100)

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
Baseline	84.5B	10.3	32.0 - 100.0	348	8.13	2	<0.001
1 Year	82.6A	13.0	20.0 - 100.0				
2 Years	81.8A	13.0	0.0 - 100.0				

Score: 100 indicates best possible quality of life

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0056 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different letters.

CORE STUDY - AUGMENTATION

Table 220: SF-36: Reported Health Transition

SF-36: Reported Health Transition
(Allowable Range 0-100)

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
Baseline	36.3A	20.7	0.0 - 75.0	315	21.72	2	<0.001
1 Year	43.0B	17.9	0.0 - 100.0				
2 Years	45.0B	18.0	0.0 - 100.0				

Score: 100 indicates best possible quality of life

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0056 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different letters.

CORE STUDY - AUGMENTATION

Table 221: MOS-20 Summary

Scale	Table	Mean Score				
			Post-Op			
		Pre-Op	1 Year	2 Years	p	Effect Size
Health Perceptions	222	92.4C	89.5B	87.3A	**	0.29
Physical Functioning	223	96.6	95.7	95.1	n.s.	--
Role Functioning	224	97.6	96.6	96.2	n.s.	--
Social Functioning	225	98.6	97.2	96.9	n.s.	--
Mental Health	226	83.1B	81.5A	80.5A	**	0.16

** = p < .001
n.s. = not significant
Significantly different means are indicated with different letters.

CORE STUDY - AUGMENTATION

Table 222: MOS-20: Health Perceptions

MOS-20: Health Perceptions
(Allowable Range 0-100)

	Descriptive Statistics			ANOVA Results			
Time	Mean	S.D.	Range	N	F	df	p
Baseline	92.4C	9.8	45.0 - 100.0	346	23.17	2	<0.001
1 Year	89.5B	13.7	20.0 - 100.0				
2 Years	87.3A	16.3	0.0 - 100.0				

Score: 100 indicates best possible quality of life

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.01 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different letters.

CORE STUDY - AUGMENTATION

Table 223: MOS-20: Physical Functioning

MOS-20: Physical Functioning
(Allowable Range 0-100)

	Descriptive Statistics			ANOVA Results			
Time	Mean	S.D.	Range	N	F	df	p
Baseline	96.6	12.3	0.0 - 100.0	350	1.92	2	0.147
1 Year	95.7	13.0	25.0 - 100.0				
2 Years	95.1	13.4	16.7 - 100.0				

Score: 100 indicates best possible quality of life

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.01 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

CORE STUDY - AUGMENTATION

Table 224: MOS-20: Role Functioning

MOS-20: Role Functioning
(Allowable Range 0-100)

	Descriptive Statistics			ANOVA Results			
Time	Mean	S.D.	Range	N	F	df	p
Baseline	97.6	12.7	0.0 - 100.0	349	1.83	2	0.161
1 Year	96.6	15.9	0.0 - 100.0				
2 Years	96.2	15.8	0.0 - 100.0				

Score: 100 indicates best possible quality of life

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.01 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

CORE STUDY - AUGMENTATION

Table 225: MOS-20: Social Functioning

MOS-20: Social Functioning
(Allowable Range 0-100)

	Descriptive Statistics			ANOVA Results			
Time	Mean	S.D.	Range	N	F	df	p
Baseline	98.6	7.7	0.0 - 100.0	352	2.80	2	0.061
1 Year	97.2	12.5	0.0 - 100.0				
2 Years	96.9	13.4	0.0 - 100.0				

Score: 100 indicates best possible quality of life

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.01 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

CORE STUDY - AUGMENTATION

Table 226: MOS-20: Mental Health

MOS-20: Mental Health
(Allowable Range 0-100)

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
Baseline	83.1B	10.5	28.0 - 100.0	351	7.70	2	<0.001
1 Year	81.5A	12.6	20.0 - 100.0				
2 Years	80.5A	13.5	12.0 - 100.0				

Score: 100 indicates best possible quality of life

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.01 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different letters.

CORE STUDY - AUGMENTATION

Table 227: Burnam Depression Screening Questions

Time	Patients Reporting Symptoms		Cochran-Mantel-Haenszel Results			
	n	%	N	Q(MH)	df	p
Two or more weeks in the past year						
Baseline	68	19.2%AB	354	8.51	2	0.014
1 Year	49	13.8%A				
2 Years	74	20.9%B				
Two or more years at any time in the past						
Baseline	22	6.2%	354	1.90	2	0.386
1 Year	27	7.6%				
2 Years	29	8.2%				
Much of the time in the past year						
Baseline	15	4.2%	354	6.43	2	0.040
1 Year	21	5.9%				
2 Years	29	8.2%				

Mantel-Haenszel Results: Results from repeated measures using the Cochran-Mantel-Haenszel General Association Statistic. When the Q(MH) statistic is significant at the 0.0167 level, post-hoc comparisons are conducted between all pairs of proportions using Scheffe's multiple comparison technique. Significantly different proportions are indicated with different letters.

CORE STUDY - AUGMENTATION

Table 228: TSCS: Physical Self

	TSOS: Physical Self (Allowable Range 18-90)						
	Descriptive Statistics			ANOVA Results			
Time	Mean	S.D.	Range	N	F	df	p
Baseline	74.4A	6.8	52.0 - 87.0	290	3.23	2	0.040
1 Year	75.4B	7.8	48.0 - 90.0				
2 Years	75.0AB	8.4	49.0 - 90.0				

TSCS: Tennessee Self Concept Scale
Score: 90 indicates best possible physical self score

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.05 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different letters.

CORE STUDY - AUGMENTATION

Table 229: Rosenberg Self-Esteem

Rosenberg Self-Esteem
(Allowable Range 10-40)

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
Baseline	36.5	3.8	16.0 - 40.0	348	2.22	2	0.109
1 Year	36.2	4.2	20.0 - 40.0				
2 Years	36.1	4.3	11.0 - 40.0				

Score: 40 indicates best possible self-esteem

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.05 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

CORE STUDY - AUGMENTATION

Table 230: Self vs. Breast Semantic Differential

	Semantic Differential (Allowable Range (-6*) to +6)						
	Descriptive Statistics			ANOVA Results			
Time	Mean	S.D.	Range	N	F	df	p
Baseline	0.0	0.5	-2.8 - 1.5	346	2.52	2	0.081
1 Year	0.0	0.3	-1.4 - 1.8				
2 Years	0.0	0.4	-1.8 - 1.6				

* Score: a negative number indicates a patient rates her breasts more positively than she rates herself.

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.05 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

CORE STUDY - AUGMENTATION

Table 231: Body Esteem Summary

Scale	Table	Mean Score Pre-Op	Post-Op 1 Year	Post-Op 2 Years	Effect p	Effect Size
Body Esteem: Total Score	232	120.9A	123.2B	123.0AB	*	0.12
Body Esteem: Sexual Attractiveness	233	49.1A	52.2B	52.3B	**	0.42
Body Esteem: Weight Concern	234	34.8	34.6	34.9	n.s.	--
Body Esteem: Physical Condition	235	37.3B	36.5A	35.9A	**	0.13

* = p < .05
** = p < .001
n.s. = not significant
Significantly different means are indicated with different letters.

Attachment 7

CORE STUDY - AUGMENTATION

Table 232: Body Esteem: Total Score

Body Esteem: Total Score
(Allowable Range 32-160)

	Descriptive Statistics			ANOVA Results			
Time	Mean	S.D.	Range	N	F	df	p
Baseline	120.9A	18.2	83.0 - 159.0	304	3.51	2	0.030
1 Year	123.2B	19.7	71.0 - 160.0				
2 Years	123.0AB	20.0	57.0 - 160.0				

Score: 160 indicates best possible total body esteem

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.05 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

CORE STUDY - AUGMENTATION

Table 233: Body Esteem: Sexual Attractiveness

Body Esteem: Sexual Attractiveness
(Allowable Range 13-65)

	Descriptive Statistics			ANOVA Results			
Time	Mean	S.D.	Range	N	F	df	p
Baseline	49.1A	7.4	29.0 - 65.0	326	46.16	2	<0.001
1 Year	52.2B	7.9	31.0 - 65.0				
2 Years	52.3B	8.0	29.0 - 65.0				

Score: 65 indicates best possible sexual attractiveness body esteem

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0167 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different letters.

CORE STUDY - AUGMENTATION

Table 234: Body Esteem: Weight Concern

	Body Esteem: Weight Concern (Allowable Range 10-50)						
	Descriptive Statistics			ANOVA Results			
Time	Mean	S.D.	Range	N	F	df	p
Baseline	34.8	8.3	14.0 - 50.0	332	0.33	2	0.722
1 Year	34.6	8.5	10.0 - 50.0				
2 Years	34.9	8.8	10.0 - 50.0				

Score: 50 indicates best possible weight concern body esteem

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0167 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

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Table 235: Body Esteem: Physical Condition

Body Esteem: Physical Condition
(Allowable Range 9-45)

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
Baseline	37.3B	5.6	20.0 - 45.0	339	11.46	2	<0.001
1 Year	36.5A	6.3	15.0 - 45.0				
2 Years	35.9A	6.8	10.0 - 45.0				

Score: 45 indicates best possible physical condition body esteem

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0167 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different letters.

CORE STUDY - AUGMENTATION

Table 236: Satisfaction Summary

Scale	Table	Mean Score: Pre-Op	Post-Op: 1 Year	Post-Op: 2 Years	p	Effect Size
Personal Life Satisfaction	237	4.9	4.8	4.8	n.s.	--
Satisfaction with Breasts	239	1.9A	4.5B	4.5B	**	3.45
How Well Breasts Matched	241	3.9A	5.2B	5.2B	**	1.05
Satisfaction with Breast Shape	243	2.4A	4.4B	4.4B	**	1.74
Satisfaction with Breast Size	245	1.9A	4.5B	4.4B	**	3.27
Satisfaction with Breast Feel or Touch	247	3.1A	4.4B	4.3B	**	1.05

** = p < .001
n.s. = not significant
Significantly different means are indicated with different letters.

CORE STUDY - AUGMENTATION

Table 237: Personal Life Satisfaction

Personal Life Satisfaction Score
(Allowable Range 1-6)

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
Baseline	4.9	0.9	1.0 - 6.0	345	2.36	2	0.095
1 Year	4.8	0.9	1.0 - 6.0				
2 Years	4.8	0.9	1.0 - 6.0				

Score: 1 = Very Dissatisfied, Unhappy Most Of The Time
2 = Generally Dissatisfied, Unhappy
3 = Sometimes Fairly Satisfied, Sometimes Fairly Unhappy
4 = Generally Satisfied, Pleased
5 = Very Happy Most Of The Time
6 = Extremely Happy, Could Not Be More Satisfied Or Pleased

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.05 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

CORE STUDY - AUGMENTATION

Table 238: Patient Rating of Personal Life Satisfaction

	%(N = 345 Patients)		
		Post-Op	
Rating	Pre-Op	1 Year	2 Years
Very Dissatisfied, Unhappy Most Of the Time	0.3%	0.3%	0.3%
Generally Dissatisfied, Unhappy	0.9%	0.6%	0.6%
Sometimes Fairly Satisfied, Sometimes Fairly Unhappy	5.8%	8.1%	9.0%
Generally Satisfied, Pleased	21.2%	19.1%	22.6%
Very Happy Most Of The Time	48.7%	50.1%	48.4%
Extremely Happy, Could Not Be More Satisfied	23.2%	21.7%	19.1%
	100.0%	100.0%	100.0%

CORE STUDY - AUGMENTATION

Table 239: Satisfaction with Breasts

Satisfaction with Breasts Score
(Allowable Range 1-5)

	Descriptive Statistics			ANOVA Results			
Time	Mean	S.D.	Range	N	F	df	p
Baseline	1.9A	0.8	1.0 - 5.0	345	1605.7	2	<0.001
1 Year	4.5B	0.7	1.0 - 5.0				
2 Years	4.5B	0.8	1.0 - 5.0				

Score: 1 = Very Dissatisfied
2 = Dissatisfied
3 = Neither Satisfied nor Dissatisfied
4 = Satisfied
5 = Very Satisfied

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.05 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different letters.

CORE STUDY - AUGMENTATION

Table 240: Patient Rating of Satisfaction With Breasts

	%(N = 345 Patients)		
		Post-Op	
Rating	Pre-Op	1 Year	2 Years
Very Dissatisfied	25.2%	0.9%	1.4%
Dissatisfied	60.9%	1.4%	2.9%
Neither Satisfied nor Dissatisfied	9.0%	2.0%	2.3%
Satisfied	4.3%	34.5%	30.4%
Very Satisfied	0.6%	61.2%	62.9%
	100.0%	100.0%	100.0%

CORE STUDY - AUGMENTATION

Table 241: How Well Breasts Matched

How Well Breasts Matched
(Allowable Range 1-6)

	Descriptive Statistics			ANOVA Results			
Time	Mean	S.D.	Range	N	F	df	p
Baseline	3.9A	1.2	1.0 - 6.0	348	227.3	2	<0.001
1 Year	5.2B	1.0	1.0 - 6.0				
2 Years	5.2B	1.0	1.0 - 6.0				

Score: 1 = Very Poor
2 = Poor
3 = Fair
4 = Good
5 = Very good
6 = Excellent

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.05 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different letters.

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Table 242: Patient Rating of How Well Breasts Matched

	%(N = 348 Patients)		
		Post-Op	
Rating	Pre-Op	1 Year	2 Years
Very Poor	2.6%	0.6%	0.3%
Poor	9.5%	2.0%	1.1%
Fair	25.6%	5.2%	5.5%
Good	28.7%	12.4%	12.9%
Very Good	25.0%	32.5%	28.7%
Excellent	8.6%	47.4%	51.4%
	100.0%	100.0%	100.0%

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Table 243: Satisfaction with Breast Shape

Satisfaction with Breast Shape
(Allowable Range 1-5)

	Descriptive Statistics			ANOVA Results			
Time	Mean	S.D.	Range	N	F	df	p
Baseline	2.4A	1.1	1.0 - 5.0	349	575.3	2	<0.001
1 Year	4.4B	1.0	1.0 - 5.0				
2 Years	4.4B	0.9	1.0 - 5.0				

Score: 1 = Very Dissatisfied
2 = Dissatisfied
3 = Neither Satisfied nor Dissatisfied
4 = Satisfied
5 = Very Satisfied

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0167 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different letters.

CORE STUDY - AUGMENTATION

Table 244: Patient Rating of Satisfaction With Breast Shape

	%(N = 349 Patients)		
		Post-Op	
Rating	Pre-Op	1 Year	2 Years
Very Dissatisfied	20.1%	0.9%	1.7%
Dissatisfied	42.4%	8.0%	5.7%
Neither Satisfied nor Dissatisfied	16.6%	4.0%	2.0%
Satisfied	15.8%	24.9%	31.5%
Very Satisfied	5.2%	62.2%	59.0%
	100.0%	100.0%	100.0%

CORE STUDY - AUGMENTATION

Table 245: Satisfaction with Breast Size

Satisfaction with Breast Size
(Allowable Range 1-5)

	Descriptive Statistics			ANOVA Results			
Time	Mean	S.D.	Range	N	F	df	p
Baseline	1.9A	0.8	1.0 - 5.0	350	1494.3	2	<0.001
1 Year	4.5B	0.8	1.0 - 5.0				
2 Years	4.4B	0.8	1.0 - 5.0				

Score: 1 = Very Dissatisfied
2 = Dissatisfied
3 = Neither Satisfied nor Dissatisfied
4 = Satisfied
5 = Very Satisfied

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0167 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different letters.

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Table 246: Patient Rating of Satisfaction With Breast Size

	%(N = 350 Patients)		
		Post-Op	
Rating	Pre-Op	1 Year	2 Years
Very Dissatisfied	29.1%	0.9%	0.9%
Dissatisfied	58.0%	4.6%	4.9%
Neither Satisfied nor Dissatisfied	8.6%	3.1%	1.4%
Satisfied	2.9%	31.4%	34.3%
Very Satisfied	1.4%	60.0%	58.6%
	100.0%	100.0%	100.0%

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Table 247: Satisfaction with Breast Feel or Touch

Satisfaction with Breast Feel or Touch
(Allowable Range 1-5)

	Descriptive Statistics			ANOVA Results			
Time	Mean	S.D.	Range	N	F	df	p
Baseline	3.1A	1.2	1.0 - 5.0	348	176.0	2	<0.001
1 Year	4.4B	1.0	1.0 - 5.0				
2 Years	4.3B	1.1	1.0 - 5.0				

Score: 1 = Very Dissatisfied
2 = Dissatisfied
3 = Neither Satisfied nor Dissatisfied
4 = Satisfied
5 = Very Satisfied

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.0167 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different letters.

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Table 248: Patient Rating of Satisfaction With Breast Feel or Touch

	%(N = 348 Patients)		
		Post-Op	
Rating	Pre-Op	1 Year	2 Years
Very Dissatisfied	11.8%	2.6%	2.9%
Dissatisfied	18.7%	5.5%	8.3%
Neither Satisfied nor Dissatisfied	29.9%	5.2%	3.7%
Satisfied	26.7%	26.7%	29.6%
Very Satisfied	12.9%	60.1%	55.5%
	100.0%	100.0%	100.0%

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Table 249: Worry About Implants At Follow-Up

Worry About Implants At Follow-Up
(Allowable Range 1-4)

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
1 Year	3.6	0.5	2.0 - 4.0	358	0.13	1	0.716
2 Years	3.5	0.5	1.0 - 4.0				

Score: 1 = Extremely Worried
2 = Very Worried
3 = Somewhat Worried
4 = Not Worried At All

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.05 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

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Table 250: Interference of Worry about Implants on Daily Activities

Interference of Worry about Implants on Daily Activities
(Allowable Range 1-4)

	Descriptive Statistics			ANOVA Results			
Time	Mean	S.D.	Range	N	F	df	p
1 Year	3.5	0.6	1.0 - 4.0	355	0.86	1	0.355
2 Years	3.5	0.7	1.0 - 4.0				

Score: 1 = Worry Interferes A Lot With Daily Activities
2 = Worry Interferes A Little With Daily Activities
3 = Worry Does Not Interfere With Daily Activities
4 = Not Worried At All

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.05 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

CORE STUDY - AUGMENTATION

Table 251: Bodily Pain Due to Implants

Bodily Pain
(Allowable Range 1-5)

Time	Descriptive Statistics			ANOVA Results			
	Mean	S.D.	Range	N	F	df	p
1 Year	4.7A	0.7	1.0 - 5.0	351	9.67	1	0.002
2 Years	4.8B	0.5	2.0 - 5.0				

Score: 1 = Extremely
2 = Quite a Bit
3 = Moderately
4 = A Little Bit
5 = Not at All

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.05 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique. Significantly different means are indicated with different letters.

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Table 252: Problems with Work/Activities Due to Implants .

	Problems (Allowable Range 1-5)						
	Descriptive Statistics			ANOVA Results			
Time	Mean	S.D.	Range	N	F	df	p
1 Year	5.0	0.2	2.0 - 5.0	356	0.33	1	0.564
2 Years	5.0	0.3	2.0 - 5.0				

Score: 1 = Extremely
2 = Quite a Bit
3 = Moderately
4 = A Little Bit
5 = Not at All

ANOVA Results: Results from repeated measures ANOVA analysis. When the ANOVA result is significant at the 0.05 level, post-hoc comparisons are conducted between all pairs of means using Tukey's multiple comparison technique.

Table 253: Frequency of Reoperation for Significant Risk Factors

Risk Factor	Total Enrolled Implants (N = 987)	Reop-erations (N = 125)	Reop-erations (%)
Incision Site			
Axillary	124	18	14.5%
Periareolar	388	44	11.3%
Inframammary	462	57	12.3%
Other	13	6	46.2%

Table 254: Relative Risk of Reoperation for Significant Risk Factors

Risk Factor	Unadjusted Risk Ratio	p-value	Adjusted Risk Ratio RR (95% CI)
Incision Site			
Axillary vs. Periareolar	1.3	0.747	- -
Inframammary vs. Periareolar	1.1	0.381	- -
Other vs. Periareolar	4.1	<0.001	5.7 (2.4, 13.3)
Axillary vs. Inframammary	1.2	0.504	- -
Other vs. Inframammary	3.8	<0.001	5.3 (2.3, 12.3)
Other vs. Axillary	3.2	0.002	4.4 (1.8, 11.2)

Table 255: Frequency of Implant Replacement/Removal for Significant Risk Factors

Risk Factor	Total Enrolled Implants (N = 987)	Explants (N = 41)	Explants (%)
Pocket Irrigation-Antibiotics			
Yes	761	26	3.4%
No	226	15	6.6%
Pocket Irrigation-Betadine			
Yes	396	10	2.5%
No	591	31	5.2%
Device Texture			
Smooth	540	34	6.3%
Textured	447	7	1.6%

Table 256: Relative Risk of Implant Replacement/Removal for Significant Risk Factors

Risk Factor	Unadjusted Risk Ratio	p-value	Adjusted Risk Ratio RR (95% CI)
Pocket Irrigation-Antibiotics			
Yes vs. No	0.5	0.005	0.4 (0.2,0.7)*
No vs. Yes	1.9		2.6 (1.3,5.0)
Pocket Irrigation-Betadine			
Yes vs. No	0.5	0.007	0.4 (0.2,0.8)*
No vs. Yes	2.1		2.8 (1.3,5.8)
Device Texture			
Smooth vs. Textured	3.9	<0.001	4.3 (1.9,9.8)

* A risk ratio < 1.0 indicates a protective risk factor.

Table 257: Frequency of Implant Rupture for Significant Risk Factors

Risk Factor	Total Enrolled Implants (N = 987)	Ruptures (N = 4)	Ruptures (%)
No significant risk factors were found.			

Table 258: Relative Risk of Implant Rupture
for Significant Risk Factors

Risk Factor	Unadjusted Risk Ratio	p-value	Adjusted Risk Ratio RR (95% CI)
No significant risk factors were found.			

Table 259: Frequency of Capsular Contracture for Significant Risk Factors

Risk Factor	Total Enrolled Implants (N = 987)	Capsular Contracture (N = 48)	Capsular Contracture (%)
No significant risk factors were found.			

Table 260: Relative Risk of Capsular Contracture for Significant Risk Factors

Risk Factor	Unadjusted Risk Ratio	p-value	Adjusted Risk Ratio RR (95% CI)
No significant risk factors were found.			

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Table 261: Frequency of Infection for Significant Risk Factors

Risk Factor	Total Enrolled Implants (N = 987)	In-fection (N = 0)	In-fection (%)

No infections occurred.

Table 262: Relative Risk of Infection for Significant Risk Factors

Risk Factor	Unadjusted Risk Ratio	p-value	Adjusted Risk Ratio RR (95% CI)
No infections occurred.			

CORE AUGMENTATION APPENDICES

APPENDIX B

Distribution of Patient Enrollment By Implanting Physician

Appendix B: Distribution of Patient Enrollment by Implanting Physician

Principal Investigator	Patients (N = 494)	
	n	%
	38	7.7%
	30	6.1%
	21	4.3%
	29	5.9%
	18	3.6%
	40	8.1%
	23	4.7%
	10	2.0%
	26	5.3%
	23	4.7%
	2	0.4%
	41	8.3%
	18	3.6%
	46	9.3%
	23	4.7%
	12	2.4%
	26	5.3%
	36	7.3%
	22	4.5%
	10	2.0%

APPENDIX C

Distribution of Product Styles By Implanting Physician

CORE STUDY - AUGMENTATION

Appendix C: Distribution of Product Styles by Implanting Physician

Implanting Physician	Total Implants Enrolled	Smooth Styles		Textured Styles		
		Round	Round	Round	Round	Shaped
		40	45	110	120	153
	n	%	%	%	%	%
	76	97.4%	0.0%	2.6%	0.0%	0.0%
	60	0.0%	0.0%	60.0%	0.0%	40.0%
	42	4.8%	4.8%	76.2%	14.3%	0.0%
	58	6.9%	0.0%	93.1%	0.0%	0.0%
	36	72.2%	5.6%	22.2%	0.0%	0.0%
	80	7.5%	40.0%	0.0%	15.0%	37.5%
	46	0.0%	34.8%	0.0%	47.8%	17.4%
	20	0.0%	0.0%	80.0%	20.0%	0.0%
	52	38.5%	61.5%	0.0%	0.0%	0.0%
	46	100.0%	0.0%	0.0%	0.0%	0.0%
	4	0.0%	0.0%	0.0%	100.0%	0.0%
	82	85.4%	7.3%	4.9%	2.4%	0.0%
	36	94.4%	0.0%	5.6%	0.0%	0.0%
	92	0.0%	0.0%	13.0%	78.3%	8.7%

CORE STUDY - AUGMENTATION

Appendix C (Cont.): Distribution of Product Styles by Implanting Physician

Implanting Physician	Total Implants Enrolled	Smooth Styles			Textured Styles		
		Round	Round		Round	Round	Shaped
		40	45		110	120	153
	n	%	%		%	%	%
	46	17.4%	0.0%		82.6%	0.0%	0.0%
	24	75.0%	0.0%		16.7%	8.3%	0.0%
	52	100.0%	0.0%		0.0%	0.0%	0.0%
	72	72.2%	27.8%		0.0%	0.0%	0.0%
	43	18.6%	23.3%		37.2%	9.3%	11.6%
	20	0.0%	0.0%		100.0%	0.0%	0.0%

APPENDIX D

List of Complications Occurring Beyond 2 Years (730 Days) Post-Implant

Appendix D: List of Complications Occurring Beyond 2 Years (730 Days) Post-Implant

Complication	# of Post 2-Year Occurrences	
	Patients (N = 16)	Implants (N = 24)
Asymmetry	1	1
Breast Pain	2	2
Bruising	0	0
Capsule Calcification	0	0
Capsular Contracture	9	14
Delayed Wound Healing	1	1
Fluid Accumulation	0	0
Hematoma	0	0
Hypertrophic Scarring	1	1
Implant Extrusion	0	0
Implant Malposition	4	5
Implant Palpability	0	0
Implant Visibility	0	0
Infection	0	0
Irritation	0	0
Loss of Nipple Sensation	0	0
Loss of Skin Sensation	0	0
Lymphadenopathy	0	0
Lymphedema	0	0
Nipple Hypersensitivity	0	0
Nipple Paresthesia	0	0
Other Abnormal Scarring	0	0
Other Nipple Related Observation	0	0

Appendix D (cont.): List of Complications Occurring Beyond 2 Years (730 Days) Post-Implant

Complication	# of Post 2-Year Occurrences	
	Patients (N = 16)	Implants (N = 24)
Pneumothorax	0	0
Ptosis	2	3
Redness	1	1
Seroma	0	0
Skin Hypersensitivity	0	0
Skin Paresthesia	0	0
Skin Rash	0	0
Swelling	0	0
Tissue or Skin Necrosis	0	0
Wrinkling/Rippling	1	1
Other Complications	1	2

APPENDIX G

2-Year Complication Rates:
Silicone-Filled Breast Implant
Core Clinical Study - Augmentation Cohort
&
1995 Saline Augmentation Clinical Study (A95)

Appendix G: 2-Year Complication Rates for Augmentation Patients in Core Study and 1995 Saline Study (A95)

Complication	Core 2-Year Risk By Patient	A95* 2-Year Risk By Patient
Reoperation	17.1% (13.7%, 20.5%)	18.2% (15.7%, 20.8%)
Swelling	6.8% (4.5%, 9.0%)	N/A
Capsular Contracture	6.7% (4.5%, 9.0%)	7.5% (5.8%, 9.3%)
Breast Pain	5.0% (3.0%, 6.9%)	14.6% (12.3%, 16.9%)
Implant Replacement/Removal	4.7% (2.8%, 6.6%)	6.1% (4.5%, 7.7%)
Loss of Nipple Sensation	3.1% (1.6%, 4.7%)	8.1% (6.3%, 9.9%)
Implant Malposition	2.5% (1.1%, 4.0%)	7.0% (5.3%, 8.7%)
Asymmetry	2.1% (0.8%, 3.4%)	9.0% (7.1%, 10.9%)
Hypertrophic Scarring	1.7% (0.5%, 2.8%)	6.1% (4.5%, 7.7%)**
Skin Rash	1.6% (0.5%, 2.8%)	1.5% (0.7%, 2.2%)
Other Nipple Related Observation	1.5% (0.4%, 2.6%)	N/A
Ptosis	1.3% (0.3%, 2.4%)	N/A
Loss of Skin Sensation	1.2% (0.3%, 2.2%)	N/A
Bruising	1.2% (0.3%, 2.2%)	N/A
Implant Rupture/Deflation	0.9% (0.0%, 1.7%)	3.5% (2.3%, 4.8%)
Other Abnormal Scarring	0.9% (0.0%, 1.8%)	6.1% (4.5%, 7.7%)**
Redness	0.8% (0.0%, 1.6%)	N/A
Hematoma	0.8% (0.0%, 1.6%)	1.6% (0.7%, 2.4%)
Other Complications	0.6% (0.0%, 1.4%)	2.1% (1.1%, 3.0%)
Delayed Wound Healing	0.6% (0.0%, 1.3%)	0.7% (0.1%, 1.2%)
Implant Palpability	0.6% (0.0%, 1.3%)	7.1% (5.3%, 8.8%)***
Seroma	0.6% (0.0%, 1.3%)	2.5% (1.5%, 3.5%)
Nipple Hypersensitivity	0.4% (0.0%, 1.0%)	N/A
Nipple Paresthesia	0.4% (0.0%, 1.0%)	9.0% (7.1%, 10.9%)
Fluid Accumulation	0.4% (0.0%, 1.0%)	N/A
Skin Paresthesia	0.4% (0.0%, 1.0%)	7.0% (5.3%, 8.7%)
Capsule Calcification	0.2% (0.0%, 0.7%)	1.2% (0.4%, 1.9%)
Lymphadenopathy	0.2% (0.0%, 0.7%)	0.2% (0.0%, 0.6%)
Lymphedema	0.2% (0.0%, 0.6%)	N/A
Implant Extrusion	0.2% (0.0%, 0.6%)	0.1% (0.0%, 0.4%)
Tissue or Skin Necrosis	0.2% (0.0%, 0.6%)	0.7% (0.1%, 1.2%)
Wrinkling / Rippling	0.2% (0.0%, 0.6%)	8.7% (6.8%, 10.5%)
Implant Visibility	0.0% --	7.1% (5.3%, 8.8%)***
Infection	0.0% --	0.7% (0.1%, 1.2%)

Appendix G (cont.): 2-Year Complication Rates for Augmentation Patients in Core Study and 1995 Saline Study (A95)

Complication	Core 2-Year Risk By Patient	A95* 2-Year Risk By Patient
Irritation	0.0% --	2.8% (1.7%, 3.9%)
Pneumothorax	0.0% --	0.1% (0.0%, 0.3%)
Skin Hypersensitivity	0.0% --	N/A

* From Original PMA Submission (PMA #P990074, November 15, 1999)

** Hypertrophic Scarring and Other Abnormal Scarring were combined and reported generally as Scarring in the 1995 Saline Study

*** Implant Visibility and Implant Palpability were combined in the 1995 Saline Study

APPENDIX H

Summary of Outcomes Following Primary Implant Removal with Replacement

Appendix H1: Summary of Complications Following Primary Implant Removal With Replacement

Complication	# of Occurrences	
	Patients (N = 3)	Implants (N = 4)
Asymmetry	0	0
Breast Pain	1	2
Breast Ptosis	0	0
Bruising	0	0
Capsule Calcification	1	2
Capsular Contracture	0	0
Delayed Wound Healing	0	0
Fluid Accumulation	0	0
Hematoma	0	0
Hypertrophic Scarring	0	0
Implant Extrusion	1	1
Implant Malposition	0	0
Implant Palpability	0	0
Implant Visibility	0	0
Infection	0	0
Irritation	0	0
Loss of Nipple Sensation	0	0
Loss of Skin Sensation	0	0
Lymphadenopathy	1	1
Lymphedema	0	0
Nipple Hypersensitivity	0	0
Nipple Paresthesia	0	0
Other Abnormal Scarring	0	0
Other Nipple Related Observation	0	0

Appendix H1 (cont.): Summary of Complications Following Primary Implant Removal With Replacement

Complication	# of Occurrences	
	Patients (N = 3)	Implants (N = 4)
Pneumothorax	0	0
Redness	0	0
Seroma	0	0
Skin Hypersensitivity	0	0
Skin Paresthesia	0	0
Skin Rash	0	0
Swelling	1	1
Tissue or Skin Necrosis	0	0
Wrinkling/Rippling	0	0
Other Complications	0	0

CORE STUDY - AUGMENTATION

Appendix H2: Patient Assessment of Secondary Implants Following Replacement of All Primary Study Devices

		Satisfaction Level* (Allowable Range 1 - 5)							
	Patients	Definitely Dissat-isfied		Somewhat Dissat-isfied		Somewhat Satisfied		Definitely Satisfied	Descriptive Statistics
Time	N	%		%		%		%	Mean	SD
6 Months	3	0.0%	0.0%	0.0%	0.0%	0.0%	100%	5.0	0.0
1 Year	9	0.0%	11.1%	0.0%	55.6%	33.3%	4.1	0.9
2 Years	14	7.1%	0.0%	0.0%	14.3%	78.6%	4.6	1.1

* Satisfaction level could range from 1 (definitely dissatisfied) to 5 (definitely satisfied).